

# EXHIBIT 2

**In Re:**

*Digitek*

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*Misbah Sherwani*

*March 18, 2010*

*Confidential – Subject to Further Confidentiality Review*

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UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -

IN RE: DIGITEK PRODUCTS : MDL NO.  
LIABILITY LITIGATION : 1968

(This document relates to all cases.)

- - -

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- - -

New York, New York  
Thursday, March 18, 2010

- - -

Videotaped Deposition of MISBAH  
SHERWANI, held at Harris Beach PLLC, 100 Wall  
Street, 24th Floor, on the above date,  
beginning at 9:06 a.m., before Kimberly A.  
Overwise, a Certified Realtime Reporter and  
Notary Public.

- - -

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10 Robert McDonald, videographer  
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13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24

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1 THE VIDEOGRAPHER: We are now  
2 on the record. My name is Robert  
3 McDonald, and I am the videographer for  
4 Golkow Technologies. Today's date is  
5 March 18th, 2010, and the time is  
6 approximately 9:06 a.m. This video  
7 deposition is being held in New York, New  
8 York, and In Re: Digitek Product  
9 Liability Litigation. The deponent is  
10 Misbah Sherwani.

11 Would counsel introduce  
12 yourselves for the record, please.

13 MR. MILLER: My name is Pete  
14 Miller from The Miller Firm representing  
15 the plaintiffs.

16 MS. CARTER: Meghan Carter from  
17 Motley Rice representing the plaintiffs.

18 MR. THOMPSON: Fred Thompson  
19 representing the plaintiffs.

20 MR. LEE: Sean Lee from Shook,  
21 Hardy & Bacon representing the Mylan  
22 defendants.

23 MR. WAMELINK: Seth Wamelink  
24 from Tucker Ellis & West representing the

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1 Actavis defendants.

2 MR. ANDERTON: Michael  
3 Anderton, also from Tucker Ellis & West,  
4 also representing the Actavis defendants.

5 THE VIDEOGRAPHER: Thank you.

6 The court reporter is Kim  
7 Overwise, and she will now swear in the  
8 witness.

9 - - -

10 ...MISBAH SHERWANI, after  
11 having been duly sworn, was examined and  
12 testified as follows:

13 BY MR. MILLER:

14 Q Good morning, ma'am.

15 A How are you?

16 Q Excellent. Thank you.

17 We met earlier. My name is Pete  
18 Miller. For the record, I'd ask you to state  
19 your full name, please.

20 A My name is Misbah Sherwani.

21 Q Yes, ma'am. And where are you  
22 currently employed?

23 A I'm currently employed at Halo  
24 Pharmaceutical.

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1 Q Halo Pharmaceutical? And what is  
2 your title at Halo?

3 A I'm the director of quality  
4 assurance.

5 Q And when did you begin your  
6 employment at Halo?

7 A November 2009.

8 Q And were you hired as a director of  
9 quality assurance in November 2009?

10 A Yes.

11 Q Then I'd like to back up before  
12 November of 2009. Where were you employed?

13 A I was employed at Actavis.

14 Q And what month did you leave  
15 Actavis?

16 A I left Actavis in October of 2009.

17 Q October of 2009. Okay. And when  
18 were you hired by Actavis?

19 A I was hired by Actavis in January of  
20 2008.

21 Q What was your title when you were  
22 first hired by Actavis in January of 2008?

23 A I was a senior manager of quality  
24 assurance investigations group.

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1 Q Senior manager of quality assurance  
2 investigation group?

3 A Correct.

4 Q Did your title change over time from  
5 January 2008 through October of 2009?

6 A Yes.

7 Q And what was the first change in  
8 your title?

9 A I was made director of quality  
10 assurance investigations group.

11 Q So you went from senior manager to  
12 director of the same group?

13 A Correct.

14 Q And when did that happen?

15 A In December of 2008.

16 Q December of 2008. Did your title  
17 change again from December 2008 until you left  
18 in 2009?

19 A No.

20 Q Have you ever been deposed before,  
21 ma'am?

22 A No.

23 Q I'd like to go through employment  
24 history prior to Actavis.

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1 Who were you employed with in 2007?

2 A I was employed by Pliva.

3 Q Could you spell that, please?

4 A P, as in Peter, L-I-V, as in Victor,

5 A.

6 Q Pliva Pharmaceuticals?

7 A It was just called Pliva,

8 Incorporated.

9 Q Okay. Was it a pharmaceutical  
10 company?

11 A Yes, it was.

12 Q Was it a pharmaceutical  
13 manufacturing company?

14 A Yes.

15 Q And what was your title there?

16 A I was the manager of quality  
17 information.

18 Q And how long were you employed at  
19 Pliva?

20 A Approximately two and a half years.

21 Q So we're going back roughly to 2005?

22 A (Witness shakes head.)

23 Q And what were you doing prior to  
24 2005?

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1           A     Prior to July of 2005, I was at  
2 Roche, Hoffmann-LaRoche.

3           Q     And what was your job title at  
4 Roche?

5           A     When I left, I was a compliance  
6 coordinator.

7           Q     When you say "compliance  
8 coordinator," does that entail or is that GMP  
9 compliance?

10          A     Yes.

11          Q     And when were you hired by Roche?

12          A     I was hired by Roche in 2003,  
13 September 2003.

14          Q     Okay. And we don't have to get  
15 exact on the month and date from here on out,  
16 but who were you employed by prior to Roche?

17          A     I was employed by Halsey Drug  
18 Company.

19          Q     You must have started when you were  
20 12. All right. Halsey Drug, what years did  
21 you work for Halsey?

22          A     I worked at Halsey from 2002 to  
23 2003.

24          Q     And what was your title there?

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1 A I was a quality auditor.

2 Q And as quality auditor at Halsey  
3 Drug, did that involve CGMP compliance?

4 A Yes.

5 Q Who did you work for before Halsey  
6 Drug?

7 A Who did I work for prior to Halsey  
8 Drug?

9 Q Yes.

10 A I worked for Penwest  
11 Pharmaceuticals.

12 Q What years did you work for Penwest?

13 A Actually, I think I'm getting my  
14 titles confused. At Halsey Drug Company, I  
15 was a compliance associate. Sorry.

16 Q That's okay.

17 A And at Penwest Pharmaceuticals, I  
18 was a quality auditor.

19 Q Okay. And when would you have  
20 started at Pensey?

21 A Penwest.

22 Q Penwest. I'm sorry.

23 A I started in 2002.

24 Q Did you work for any pharmaceuticals

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1 prior to Penwest?

2 A Yes. Barr Laboratories.

3 Q Okay. What was your job title  
4 there?

5 A I was a chemist.

6 Q And as a chemist, you were certainly  
7 concerned with or adhered to CGMP compliance?

8 A Yes.

9 Q Okay. I'd like to just do a couple  
10 quick questions about your education.

11 Where did you go to college?

12 A I went to New York University.

13 Q Okay. And what did you study at  
14 New York?

15 A I studied sciences.

16 Q Okay. And what's your degree?

17 A I have a Bachelor of Arts in biology  
18 and history.

19 Q What year did you graduate?

20 A I graduated in 1998.

21 Q Any education beyond NYU?

22 A Yes.

23 Q What was that, ma'am?

24 A I have a Master's of Industrial

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1 Pharmacy from Long Island University.

2 Q And what year did you receive that?

3 A In 2002.

4 Q Being that you haven't been deposed  
5 before, I'd like to just go over a couple of  
6 quick rules. It's important that you  
7 understand my questions. So as we go  
8 throughout the deposition, if I ask a question  
9 and you don't understand it, I'm going to ask  
10 that you ask me to rephrase the question. Is  
11 that fair?

12 A Yes.

13 Q And make sure we don't step on each  
14 other when we're talking, so sometimes it  
15 takes me a second to get my question out. So  
16 let me get my full question out before you  
17 answer it so she can type it up.

18 Is that fair?

19 A Yes.

20 Q Okay. Fantastic. How did it come  
21 to be that -- or I guess my question is this:  
22 Is it "Pliva" or "Pliva"?

23 A "Pliva."

24 Q You left Pliva in December of 2007,

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1 started with Actavis January 2008. Why was it  
2 you left Pliva in search for employment?

3 A It was just a better opportunity.

4 Q Okay. And how did you hear about  
5 that opportunity with Actavis in January of  
6 2008?

7 A There -- well, actually there were a  
8 few job postings on a couple of search sites,  
9 job search sites, for Actavis. And I had a  
10 couple of internal individuals who worked  
11 there who had apprised me of an opportunity.

12 Q There were individuals at Actavis  
13 that you knew prior to being employed there?

14 A Yes.

15 Q And who would that be?

16 A I knew Phyllis Lambridis.

17 Q Okay. Anyone else?

18 A Yes. Elisabeth Guarch.

19 Q Would you spell that for me?

20 A E-L-I-S-A --

21 Q Oh, Elisabeth I got. The last name.

22 A Guarch is G-U-A-R-C-H.

23 Q Was there anyone else?

24 A There were quite a few --

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1 Q Okay.

2 A -- that I have met prior.

3 Q That you met prior?

4 A Right.

5 Q How did you know Mrs. Lambridis  
6 prior to your employment?

7 A I have actually worked with her at  
8 prior companies.

9 Q Okay. Which companies?

10 A I worked with her at Halsey Drug  
11 Company and at Pliva.

12 Q Who did you interview with in order  
13 to be employed at Actavis? Or did you have --  
14 I guess I should start out with saying: Did  
15 you have an interview before you were hired?

16 A Yes.

17 Q And who did you interview with?

18 A I interviewed with Scott Talbot,  
19 Tony Delicato. I interviewed with Bill  
20 Washington, Chris Young, Brian Nizio, Scott  
21 Allen, Rick Dowling, and Swapan Roychowdhury.

22 Q Quite the interview process. Did  
23 this take place everyone in one room at one  
24 time or did you interview with all these

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1 people individually?

2 A I interviewed with them  
3 individually.

4 Q During this interview process when  
5 you sat with all these individuals, was it --  
6 was there ever a time when any one of those  
7 individuals shared with you the current  
8 compliance status of the company?

9 A I don't recall.

10 Q What did you know about Actavis  
11 going into your employment in January 2008  
12 specifically regarding their compliance  
13 history?

14 A What I knew was they had a few  
15 warning letters that had been issued to them  
16 for their Little Falls Totowa facility. And I  
17 knew that they had done extensive remediation  
18 at their Elizabeth site for prior 483s that  
19 they had received.

20 Q Okay. So you were familiar with  
21 483s at Elizabeth and familiar with  
22 remediation that was done there; is that  
23 correct?

24 A Familiar in the sense that I had

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1 read whatever was on the Internet on the FDA  
2 website.

3 Q Okay. And then you did that  
4 research prior to your employment?

5 A Yes.

6 Q Was that in preparation of the  
7 interview process?

8 A Yes.

9 Q And what opinion, if any, did you  
10 form regarding Actavis' prior CGMP compliance  
11 when you read the warning letters --

12 MR. ANDERTON: Objection.

13 BY MR. MILLER:

14 Q -- off the Internet?

15 MR. ANDERTON: Objection.

16 You may answer.

17 THE WITNESS: Can you just ask  
18 the question again?

19 BY MR. MILLER:

20 Q Certainly. When you read the  
21 warning letters off the Internet that regarded  
22 Actavis' CGMP compliance, what opinion did you  
23 form regarding their past history on the same  
24 topic?

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1 MR. ANDERTON: Objection.

2 You may answer.

3 THE WITNESS: There was really  
4 no opinion that I formed. Like I said,  
5 it was just to prepare myself for the  
6 interview.

7 BY MR. MILLER:

8 Q FDA is charged with ensuring  
9 pharmaceutical manufacturing companies are  
10 within CGMP compliance; do you agree with that  
11 statement?

12 A Yes.

13 Q And do you agree that an inspection  
14 of the facilities for a pharmaceutical  
15 manufacturing company is the process by which  
16 the FDA ensures that there's CGMP compliance?  
17 Do you agree with that?

18 A Among other things.

19 Q Among other things?

20 A Correct.

21 Q And I like to use the term "483  
22 inspection," but I'm learning that perhaps  
23 that's not the right term.

24 What term do you use for the

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1 inspection the FDA conducts of a  
2 pharmaceutical manufacturing company.

3 A It honestly depends on what type of  
4 inspection they're conducting.

5 Q Okay. Are you familiar with the  
6 inspections that were conducted that resulted  
7 in the warning letters that you read on the  
8 Internet?

9 A Yes. Those would be, if I recall  
10 correctly, I believe they would be GMP, CGMP  
11 inspections.

12 Q CGMP inspections, that's the term  
13 you want -- okay. We'll use that term. Did  
14 you, prior to employment in preparing for the  
15 interview or at any time during your  
16 employment, have an opportunity to go back and  
17 read what I'll call the FDA 483s or the CGMP  
18 inspection report that were conducted on  
19 Actavis? And there were multiple, so I'm  
20 asking about any of them.

21 A You're asking afterwards if I had a  
22 chance --

23 Q At any time.

24 A As I indicated to you, I briefly

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1 reviewed what was on the FDA website.

2 Q You indicated to me that's what you  
3 did in preparation for potential employment.  
4 And my question is much broader. It's at any  
5 time, as we sit here right now, yesterday,  
6 going all the way back to your review in  
7 preparation for employment, have you had an  
8 opportunity to sit down and read the CGMP  
9 inspection write-up from the FDA regarding the  
10 Actavis Little Falls?

11 A For what -- for which inspection?

12 Q Any inspection.

13 A Yes.

14 Q Okay. And did that take place after  
15 you were employed?

16 A No.

17 Q When did it take place?

18 A While I was employed at Actavis.

19 Q Okay. So you did it as part of your  
20 work title?

21 A Again, I just want to clarify if I'm  
22 understanding correctly. You asked me if I  
23 had an opportunity to review any of the CGMP  
24 inspection reports --

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1 Q Right.

2 A -- that were conducted at the  
3 facility.

4 Q Yes.

5 A I did, yes.

6 Q Okay. Great. Explain to me what  
7 duties and responsibilities go with the title  
8 of senior manager of the QA investigation  
9 group.

10 A I was responsible for overseeing the  
11 investigations, the corrective actions and  
12 preventive actions. I was responsible for the  
13 complaints. I was responsible for issuing  
14 field alerts.

15 Q And when you say responsible for  
16 investigations, is that laboratory  
17 investigations such as out-of-specification  
18 findings?

19 A Those are one type.

20 Q What other types of investigations  
21 other than out-of-specification  
22 investigations?

23 A Any process-related investigations.

24 Q You don't have to do an exhaustive

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1 list, but can you give me a few examples?

2 A Anything that pertains to  
3 manufacturing, packaging.

4 Q And when you say you're responsible  
5 or that falls under your job title, how  
6 exactly does that work? If the lab finds an  
7 out-of-specification while doing lab testing,  
8 is it the laboratory that would initiate the  
9 investigation and then you maintain the file  
10 or do you monitor it to make sure it's  
11 completed? I need kind of your words on how  
12 you follow the investigations.

13 A Okay. My responsibility is  
14 basically to review and -- review, approve,  
15 and bring to closure any investigations that  
16 were initiated.

17 So in the example that you cited, if  
18 there was an out-of-specification that was  
19 observed by the laboratory, they would  
20 initiate the deviation; we would track it,  
21 trend it, and basically, as I indicated to  
22 you, review; and I would approve the  
23 investigation.

24 Q "Track it" means to keep a file of

1       that type of investigation?

2             A       Correct.

3             Q       And "trend" means that if it happens  
4       more than once, you want to know if the same  
5       thing is happening over and over again?

6             A       Correct.

7             Q       Okay. And "approve it," you approve  
8       the procedures that the QA department is  
9       taking regarding the inspection?

10            A       I'm sorry?

11            Q       Well, what do you mean by "approve"?

12            A       Approve in the sense that when the  
13       investigation report is written, I would  
14       review it, ensure that it was accurate, it was  
15       thorough, it met all of the criteria  
16       regarding, you know, as far as internal  
17       requirements, any sort of regulatory  
18       requirements. And once those aspects were  
19       met, I would approve.

20            Q       And then "bring to closure," how  
21       does an investigation receive closure?

22            A       Well, first of all, the  
23       investigation report, like I indicated to you,  
24       is approved. So that aspect of it is -- that

1 report is closed. However, if there are any  
2 further actions, whether they be corrective  
3 actions or preventive actions, that are  
4 associated with that report, you have to  
5 ensure that those actions are completed.

6 Once those are completed and  
7 everything pertaining to the actions related  
8 to the investigation are completed, then  
9 that's what "bring to closure" means.

10 Q Okay. And when you say "preventive  
11 action," if the company determines that  
12 there's something that can be done to not  
13 allow this out-of-specification to happen  
14 again, then you would ensure that the company  
15 takes those steps?

16 A To prevent recurrence.

17 Q Yes. Okay. Whose spot did you  
18 replace -- that's not a great way to put it.  
19 But who was in the -- who held that title as  
20 senior manager of QA investigations group  
21 prior to your being hired in January of 2008?

22 A I don't know.

23 Q Did you receive any kind of  
24 pass-down? Did somebody sit down with you and

1 say, "This is the status of our investigations  
2 to date; we want you to take over"? Or did  
3 you just sit down and start from then on and  
4 not have a pass-down?

5 A No. I mean, there's a certain  
6 amount of pass-down that does occur. It's a  
7 rolling list. So obviously there was that  
8 information that was passed that here is the  
9 current status of investigations that I would  
10 be responsible for.

11 Q Who did that pass-down with you?

12 A Who did that? For the Elizabeth  
13 site, it was Tony Delicato. And for the  
14 Little Falls site, it was a combination of  
15 Scott Talbot and Dan Bitler.

16 Q And for Elizabeth, did that  
17 primarily pertain to adverse drug event  
18 reporting? Is that correct?

19 A I'm sorry?

20 Q What do you -- what term do you use  
21 for complaints received from customers  
22 regarding the products?

23 A There are a few types.

24 Q Okay.

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1           A     There are product complaints, which  
2     is what I was responsible for. And that  
3     entails any customer complaints that we  
4     received regarding the quality of the product.  
5     So, for example, if they saw broken tablets or  
6     if they saw a burnt induction seal or if they  
7     saw a damaged bottle that they received, those  
8     are product quality complaints.

9           Q     Okay.

10          A     There are adverse events. Those are  
11     the responsibility of the medical affairs  
12     group. And that would entail any sort of  
13     obviously adverse event related to the  
14     product.

15          Q     And who was your counterpart that  
16     was responsible for the adverse events?

17          A     Sarita Thapar.

18          Q     My question is: Were those product  
19     complaints and adverse events, were they all  
20     maintained at Elizabeth?

21          A     What do you mean by "all"? Like --

22          Q     What do I mean by "all"? You said  
23     that your pass-down at Elizabeth was from  
24     Delicato. Was the pass-down for Elizabeth,

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1 was it regarding how you're going to handle  
2 and pass complaints for the product? Were the  
3 product complaints, was that an issue that was  
4 dealt with at Elizabeth or Little Falls?

5 A They're two different facilities.

6 Q Right.

7 A Each facility had a different  
8 product listing. So dependent on what site  
9 manufactured or packaged or processed what  
10 product, the product complaint would reside at  
11 that facility.

12 Q Oh, okay. So the product -- you  
13 understand that today we're here to speak  
14 about the product Digitek?

15 A Yes.

16 Q Okay. And what's the active  
17 ingredient in Digitek?

18 A Digoxin.

19 Q Okay. And which plant was Digitek  
20 manufactured?

21 A In the Little Falls and Totowa  
22 facilities.

23 Q And does that mean that Little Falls  
24 would have maintained the file on the product

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1 complaints and the adverse events?

2 A They would have maintained the files  
3 for the product complaints.

4 Q Would the adverse events have been  
5 maintained at Elizabeth?

6 A Yes.

7 Q Thank you. Who did you report to?  
8 Who was the director of the quality assurance  
9 investigations group when you were hired in  
10 January of 2008?

11 A There was no director of quality  
12 assurance investigations group.

13 Q Okay. Then do you have an  
14 understanding as to why at the end of the  
15 year, December of 2008, a billet or job title  
16 of director was created?

17 A There was a reorganization at the  
18 company. That was a position that was newly  
19 created.

20 Q I am going to hand you what was  
21 previously marked as Plaintiff's Exhibit 91.  
22 Ma'am, if you'll take a look at that document,  
23 and I'll represent to you that that is an  
24 establishment inspection report from the FDA.

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1 Are you familiar with what that is?

2 A With what an establishment  
3 inspection report is?

4 Q Yes, ma'am.

5 A Yes.

6 Q Those previous companies that you  
7 worked for, were you ever involved with the  
8 CGMP inspections, if any, that were conducted?

9 A Yes.

10 Q Okay. And have you had experience  
11 in the past to actually work with the FDA  
12 inspectors?

13 A Yes.

14 Q And have you in the past prior to  
15 Actavis been involved in a warning letter that  
16 was the result of a CGMP inspection?

17 A No.

18 Q Have you had an opportunity to  
19 review establishment inspection reports in the  
20 past?

21 A Yes.

22 Q So you're familiar with what one is?

23 A Correct.

24 Q Okay. Turn to -- this is an

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1 establishment inspection report from an  
2 inspection that took place in May of 2008.  
3 And you were employed at Actavis at that time?

4 A Correct.

5 Q Are you familiar with that  
6 particular inspection?

7 A Yes.

8 Q Have you seen this document before?

9 A No.

10 Q All right. Well, take a look at it.  
11 And we're going to go to Page 12. And in this  
12 establishment inspection report written by the  
13 FDA, they identify the individuals that were  
14 employed at Actavis that were important  
15 regarding this CGMP inspection.

16 And I would like to ask you about  
17 the paragraph at the bottom of Page 12 that  
18 identifies you. Do you see where it starts  
19 out with your name, ma'am?

20 A Correct.

21 Q And it says: "Misbah Sherwani,  
22 Senior Manager Quality Assurance  
23 Investigations Group, joined the company" --  
24 and it's redacted but you agree that should

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1 say January of 2008?

2 A Correct.

3 Q "She currently oversees Quality  
4 Assurance investigations and complaints for  
5 multiple sites, including Totowa, Little  
6 Falls, and Elizabeth, New Jersey. She  
7 explained the efforts to correct the backlog  
8 of incomplete QA investigations and stated  
9 that she hoped to hire additional resources."

10 My question, ma'am: Do you recall  
11 sitting and having conversations with the FDA  
12 inspector on this inspection?

13 A Yes.

14 Q And which inspector do you remember  
15 sitting and talking with?

16 A I spoke to Erin McCaffery.

17 Q And do you recall the conversation  
18 with Erin regarding the backlog of incomplete  
19 QA investigations?

20 A To an extent.

21 Q Okay. And what was it that you  
22 explained to Erin regarding the backlog of  
23 incomplete QA investigations?

24 A In what regard?

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1           Q     In any regard. What conversation do  
2     you recall having with her regarding the  
3     incomplete QA investigations?

4           A     I think it was exactly that, how  
5     many incomplete investigations there were,  
6     what the status of them were. I think that  
7     was the general conversation.

8           Q     According to Actavis' investigations  
9     SOP, do you know how many days an  
10    investigation is supposed to be wrapped up or  
11    completed?

12          A     Which SOP are you referring --

13          Q     SOP 33, the one regarding  
14    out-of-specification investigations.

15          A     There --

16                   MR. ANDERTON: Objection.

17                   You may answer.

18                   THE WITNESS: There were quite  
19    a few revisions, so I'd actually have to  
20    see which revision.

21    BY MR. MILLER:

22          Q     And it's your memory that in the  
23    revisions, the number of days that you have to  
24    complete the investigation changed?

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1 MR. ANDERTON: Objection. If  
2 you want to ask her about a document, can  
3 we put it in front of her?

4 MR. MILLER: No. I don't have  
5 it right now.

6 BY MR. MILLER:

7 Q I'm asking about your memory. Do  
8 you have a memory of the number of days that  
9 an investigation was to be completed changed  
10 in a revision?

11 A Yes.

12 Q Do you remember what the number of  
13 days changed to?

14 A It changed from 30 business days to  
15 30 calendar days.

16 Q And from 30 business days to  
17 calendar days. So 30 business days, you'd  
18 agree with me that's counting Monday through  
19 Friday?

20 A Correct.

21 Q And calendar days, day one is when  
22 the investigation started. You've got 30  
23 days. So it actually shortened; do you agree  
24 with that?

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1 A Correct.

2 Q Do you remember roughly when that  
3 change took place?

4 A I believe that took place in June of  
5 2008.

6 Q Do CGMPs -- have you had an  
7 opportunity to read the good manufacturing  
8 practices, or do you keep a copy of them with  
9 you at work?

10 A Yes.

11 Q I guess that was bad because I asked  
12 two questions. Have you read the good  
13 manufacturing practices?

14 A Have I read? Certain portions of  
15 it, yes.

16 Q Okay, great. And you do keep a copy  
17 at work?

18 A Yes.

19 Q And do you agree that part of  
20 compliance with good manufacturing practices  
21 is that a company follows its own standard  
22 operating procedures?

23 A Yes.

24 Q The second half of that sentence

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1       that we read that says "she hoped to hire  
2       additional resources," do you recall the  
3       requirement or the desire to hire additional  
4       resources back when you spoke with this  
5       investigator between March and May of 2008?

6             A       I'm sorry. Ask that again.

7             Q       Certainly. I'll read the whole  
8       sentence: "She explained the efforts to  
9       correct the backlog of incomplete QA  
10       investigations and stated that she hoped to  
11       hire additional resources."

12                    Did you hope to hire additional  
13       resources back in the time frame of May of  
14       2008?

15             A       Yes.

16             Q       What was -- what positions needed to  
17       be filled?

18             A       It wasn't a -- I don't believe that  
19       there were any open positions that needed to  
20       be filled. However, given the workload, I had  
21       requested additional resources.

22             Q       Given the workload, and is that  
23       workload the incomplete or the backlog of  
24       incomplete QA investigations?

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1           A     That was one of the items.

2           Q     It goes on to say: "She explained  
3     the limitations of the current paper based  
4     system to document the QA investigations. She  
5     described plans to implement the electronic  
6     Trackwise system, which is already in use at  
7     the Actavis Elizabeth, New Jersey, site."

8                     Now, ma'am, my question is: Explain  
9     to me what you believe the limitations of the  
10    paper-based system to be.

11          A     There were limitations in regards to  
12    how quickly and efficiently you would be able  
13    to search, track, and monitor information.

14          Q     So as we discussed, one of your job  
15    titles was to track out-of-specification  
16    investigations. And it's my understanding  
17    that with a paper-based system, it was  
18    difficult to go back and review and see what  
19    other out-of-specifications were related to  
20    the one you were currently working on?

21                     MR. ANDERTON: Objection;  
22                     mischaracterizes her testimony.

23                     You may answer.

24                     THE WITNESS: I'm sorry?

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1 MR. ANDERTON: You may answer.

2 THE WITNESS: I didn't say it  
3 couldn't be done. It was more of an  
4 efficient manner. So sometimes it would  
5 be a bit more time consuming.

6 BY MR. MILLER:

7 Q I understand. And the TrackWise  
8 system, that was an electronic system so that  
9 you could go back and track  
10 out-of-specification issues much faster?

11 A Yes.

12 Q Do you know how long it had been in  
13 place at Actavis Elizabeth?

14 A No.

15 Q It goes on to say: "Ms. Sherwani  
16 was also responsible for providing the  
17 voluntary recall information to New Jersey  
18 District Office."

19 Was that a part of your job  
20 description when you were hired in January of  
21 2008, or did someone come to you during the  
22 decision to recall and inform you that that  
23 was going to be part of your job title?

24 A No, it wasn't part of my job

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1 description when I was hired. However, given  
2 my prior experience with recalls, I was  
3 requested to help.

4 Q What prior experience with recalls  
5 did you have, ma'am?

6 A I performed recalls for  
7 Hoffmann-LaRoche and for Pliva.

8 Q And were those voluntary recalls, or  
9 were they directed by the FDA?

10 A All recalls are voluntary.

11 Q All recalls are voluntary?

12 A They should be. It's really at the  
13 company -- the FDA really can't force a  
14 recall. It's more of a company directive.

15 Q And you're familiar with the fact  
16 that the CGMP is a federal code, 210 and 211?

17 A Yes.

18 Q Yes?

19 A Uh-huh.

20 Q Have you read the section on  
21 recalls?

22 A Yes.

23 Q You have? Okay. Are you familiar  
24 with recalls being either voluntary, totally a

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1 decision on the part of the company and -- or  
2 the other option being that the FDA recommends  
3 the recall and then the company does a  
4 voluntary recall based on the recommendation  
5 of the FDA? Are you familiar with that split?

6 MR. ANDERTON: Objection.

7 You may answer.

8 THE WITNESS: I'm sorry. Ask  
9 that again.

10 BY MR. MILLER:

11 Q Certainly. Would you agree that  
12 there are voluntary recalls without any input  
13 whatsoever from the FDA and there are recalls  
14 in which the FDA recommends that the company  
15 recall and, therefore, the company does a  
16 voluntary recall?

17 A In my experience, it has always been  
18 the company that performs a voluntary recall.

19 Q What recalls were you involved with  
20 with Actavis?

21 A Quite a few.

22 Q And would you agree with the  
23 statement that these recalls are a result of  
24 the CGMP inspection that took place at Actavis

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1 in May of 2008?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: Are these recalls  
5 a result of the inspection?

6 BY MR. MILLER:

7 Q Yes.

8 A To an extent.

9 Q Do you know what a Class I recall  
10 is?

11 A Yes.

12 Q What's a Class I recall?

13 A A Class 1 recall is a recall down to  
14 the consumer level.

15 Q And you agree it's more serious than  
16 the other classes of recall?

17 A It's -- yes.

18 Q Did you have experience with a  
19 Class I recall prior to Actavis, the recalls  
20 from Hoffmann-LaRoche and Pliva?

21 A Yes.

22 Q Which one?

23 A At Hoffmann-LaRoche.

24 Q Was it a particular lot, or was it

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1 all lots back at Hoffmann-LaRoche?

2 A It was one particular lot.

3 Q So you agree with me that -- well,  
4 Digitek was one of the recalls you were  
5 involved with at Actavis; correct?

6 A Yes.

7 Q And you agree that it was a Class 1?

8 A Yes.

9 Q And you agree that it was all lots?

10 A Yes.

11 Q Why was Digitek recalled?

12 A Why was Digitek -- in what regard?  
13 To one particular lot or all lots?

14 Q I'm asking, ma'am. I don't know.  
15 Why was Digitek recalled?

16 A I don't know.

17 Q You don't know?

18 A (Witness shakes head.)

19 Q Do you agree with this last  
20 statement that I read from the FDA EIR report  
21 that states that Ms. Sherwani was also  
22 responsible for providing the recall  
23 information to New Jersey district office? Is  
24 that a true statement?

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1 A For certain recalls, yes.

2 Q Is the Digitek recall one of the  
3 recalls?

4 A Yes.

5 Q Did you feel like it was important  
6 that you determine why Digitek was recalled if  
7 you're going to communicate to the FDA  
8 regarding providing the voluntary recall  
9 information to their district office?

10 MR. ANDERTON: Objection.

11 BY MR. MILLER:

12 Q It's okay to answer.

13 MR. ANDERTON: You may answer.

14 THE WITNESS: I was only  
15 carrying out what I was told to do.

16 BY MR. MILLER:

17 Q The next statement says: "She  
18 reports to Phyllis Lambridis, Vice President  
19 US Quality and Compliance."

20 Was Phyllis Lambridis the one  
21 telling you what to do when it came to the  
22 recall?

23 A She was one of the individuals,  
24 except that is incorrect. I didn't report to

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1 Phyllis Lambridis.

2 Q Who did you report to?

3 A I reported to Tony Delicato.

4 Q Okay. Although you reported to Tony  
5 Delicato, you agree that Phyllis Lambridis was  
6 giving you input as far as the recall goes?

7 A She was one of the individuals, yes.

8 Q Anyone else besides Phyllis  
9 Lambridis and Delicato?

10 A There were other management.

11 Q Any names come to mind?

12 MR. ANDERTON: You can identify  
13 the people.

14 THE WITNESS: Okay.

15 MR. ANDERTON: You can tell  
16 them -- to the extent that you're  
17 concerned about privileged  
18 communications, you can tell them  
19 in-house counsel or outside counsel that  
20 gave you. Just don't reveal any of the  
21 information they gave you. You can  
22 identify them, not the substance of the  
23 communications.

24 THE WITNESS: Okay.

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1 MR. ANDERTON: Okay?

2 THE WITNESS: I worked with a  
3 group of individuals: Phyllis Lambridis,  
4 Tony Delicato, John LaRocca, Hjordis  
5 Arnadottir. I don't know if I'm not --  
6 I'm not pronouncing her name correctly.  
7 But they were a few of the individuals  
8 that I interacted with.

9 BY MR. MILLER:

10 Q Thank you. How many times during  
11 the CGMP compliance investigation, the 483,  
12 did you actually sit and talk with the  
13 investigator?

14 A You're asking for this particular  
15 inspection --

16 Q Yes.

17 A -- how many times? I sat with her,  
18 I believe, just once.

19 Q And did the investigator you sat  
20 with, did she seem satisfied with your  
21 responses regarding the backlog of incomplete  
22 QA investigations?

23 MR. ANDERTON: Objection.

24 You may answer.

1 THE WITNESS: I wouldn't know.

2 You'd have to ask her.

3 BY MR. MILLER:

4 Q No. Did she seem satisfied to you?  
5 I'm asking what your opinion of the  
6 conversation was.

7 MR. ANDERTON: Objection; asked  
8 and answered.

9 BY MR. MILLER:

10 Q It's okay to answer.

11 A Again, I --

12 Q I'd have to ask her what your  
13 opinion of the conversation was? I'm not so  
14 sure she'd have that answer.

15 A No, I don't know. I mean, as far as  
16 you're asking me if she seemed satisfied?

17 Q Yes.

18 A I don't know. I never asked her if  
19 she was satisfied.

20 Q One of the duties or descriptions of  
21 your job were to handle complaints. And tell  
22 me if there is any connection there between  
23 investigations such as out-of-specifications  
24 and complaints. They seem like two totally

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1 separate jobs. Am I correct in thinking that?

2 A It's actually -- it depends. There  
3 may be some correlation.

4 Q During January 2008 up and to the  
5 completion of this inspection in the end of  
6 May of 2008, how much time would you spend on  
7 those two tasks, either complaints or  
8 investigations? How was your day, your  
9 typical day split up?

10 A The majority of my day was spent  
11 with investigations from that time frame, from  
12 January 2008 to May 2008.

13 Q And then you said also you dealt  
14 with field alerts. What are field alerts?

15 A Field alerts are communications from  
16 the company to the FDA to alert them of  
17 significant quality issues.

18 Q Did you generate the field alerts  
19 and make sure they were sent to the FDA or  
20 someone else generated them and you tracked  
21 them?

22 A Initially I was not doing that.  
23 That's a responsibility that came to me  
24 probably sometime in June of 2008.

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1 Q Prior to June of 2008, would you  
2 have been involved in any way in field alerts?

3 A There were a few that I had been  
4 reviewing.

5 Q Were you reviewing any field alerts  
6 that dealt with Digitek in 2008?

7 A I don't recall.

8 Q Do you recall any field alerts being  
9 issued to the FDA regarding Digitek while you  
10 were employed at Actavis?

11 A I don't recall.

12 Q Do you have a memory of generating  
13 any field reports to the FDA since you've been  
14 employed at Actavis?

15 A Yes.

16 Q Okay. I don't want to know the name  
17 of the drug. It's not important. But what  
18 was the issue with the drug if you can give me  
19 an example of a field report that you've  
20 submitted to the FDA?

21 MR. ANDERTON: Objection. I'm  
22 not going to let you get around PTO 27  
23 like that. You can ask her issues for  
24 field alerts about digoxin. But to the

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1 extent you're explicitly asking about  
2 issues, even though you're not  
3 identifying the specific drug, that's  
4 asking about an issue relating to a drug  
5 other than digoxin, just not naming the  
6 drug.

7 So I'm going to instruct the  
8 witness to answer only with respect to  
9 Digitek.

10 BY MR. MILLER:

11 Q Are you being represented by counsel  
12 today?

13 A The company -- he is not my lawyer.  
14 He is a company-provided --

15 Q Do you have a lawyer here at all  
16 today?

17 A No.

18 MR. ANDERTON: The rule clearly  
19 allows me to instruct a witness or  
20 deponent to not answer a question to the  
21 extent necessary to enforce the terms of  
22 a court order. It's not limited to  
23 whether I represent her or not. The rule  
24 is very clear on that.

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1 MR. THOMPSON: What rule are  
2 you talking about?

3 MR. ANDERTON: 30(b)(2), I  
4 believe, is the rule -- 30(c)(2), I  
5 misspoke, clearly allows me to instruct a  
6 witness to not answer, whether I  
7 represent that person or not.

8 MR. THOMPSON: I'm going to  
9 have to look that up, but I think that's  
10 relating to privilege. You are asserting  
11 relevance.

12 MR. ANDERTON: I'm not  
13 asserting relevance. I'm enforcing the  
14 terms of a court order.

15 MR. THOMPSON: We disagree on  
16 PTO 27. So my suggestion would be for  
17 Mr. Miller to ask the questions and you  
18 to assert the objection and direction so  
19 we'll have a record.

20 MR. ANDERTON: Which is fine.  
21 Give me one second.

22 MR. MILLER: Let's go off the  
23 record for a second.

24 THE VIDEOGRAPHER: Off the

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1 record at 9:59 a.m.

2 (Short recess.)

3 THE VIDEOGRAPHER: Back on the  
4 record at 10:03.

5 BY MR. MILLER:

6 Q Ma'am, did you have any  
7 conversations with any of the attorneys while  
8 we took that break?

9 A Yes.

10 Q And what did you discuss while you  
11 were on the break?

12 MR. ANDERTON: You can answer.

13 THE WITNESS: Oh, he was just  
14 asking me if I recalled specifics of any  
15 field alerts that I issued.

16 BY MR. MILLER:

17 Q Okay. And your answer?

18 A Yes.

19 Q Okay. I want to ask you, did any of  
20 the field alerts that you submitted during  
21 your employment at Actavis, did they regard  
22 CGMP compliance issues?

23 MR. ANDERTON: I'm going to  
24 object.

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1 But you may answer.

2 THE WITNESS: What do you mean  
3 by "issues"?

4 BY MR. MILLER:

5 Q Did they regard CGMP compliance?

6 A In what regards?

7 Q Any regard.

8 MR. ANDERTON: I'm going to  
9 object and ask you, Pete, to form your  
10 questions so as to make clear any  
11 distinction between Actavis Totowa and  
12 Actavis Elizabeth.

13 I think the testimony has shown  
14 that Ms. Sherwani had responsibility --  
15 responsibilities both for Actavis Totowa  
16 and Actavis Elizabeth operations.

17 And I think it's important for  
18 the record to properly reflect, rather  
19 than just a general Actavis denomination,  
20 whether we're talking about Elizabeth or  
21 Totowa.

22 BY MR. MILLER:

23 Q Did any of the field reports that  
24 you generated while at Actavis, did they

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1 involve CGMP compliance? And I'm only asking  
2 about field alerts at Actavis Little Falls or  
3 Actavis Elizabeth if they involved adverse  
4 events.

5 MR. ANDERTON: I object to the  
6 form. That's at least two questions,  
7 maybe more.

8 You can answer if you  
9 understand.

10 THE WITNESS: No. Can you  
11 restate your question?

12 MR. ANDERTON: Pete, just one  
13 question at a time would be much easier  
14 for all concerned.

15 MR. MILLER: Sounds nice.

16 BY MR. MILLER:

17 Q Did you write any field alerts that  
18 concerned CGMP compliance while you were  
19 employed at Actavis?

20 A Did I write any field alerts? Yes.

21 Q Did you have a feeling that this had  
22 something to do with safety?

23 MR. ANDERTON: Objection.

24 You may answer.

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1 THE WITNESS: I wouldn't know.  
2 That's not my area. I was only -- as I  
3 indicated to you before, field alert  
4 reports are communications between the  
5 FDA and the company for any potential  
6 significant quality issues.

7 BY MR. MILLER:

8 Q Is safety your area in any of your  
9 job titles?

10 MR. ANDERTON: Objection.

11 You may answer.

12 THE WITNESS: One of the  
13 aspects of quality to ensure a quality  
14 product is to ensure safety, but that's  
15 a -- that's a requirement for the entire  
16 company. It's...

17 BY MR. MILLER:

18 Q It's a requirement for you too;  
19 right, ma'am?

20 A Correct.

21 Q If no one investigated  
22 out-of-specification findings and a product  
23 was just made whether or not there were  
24 out-of-specification tests or not, would it

1 still be a safe product?

2 A I'm sorry. Say that again.

3 Q Certainly. If a pharmaceutical  
4 manufacturing company didn't have someone such  
5 as yourself or an investigation group to  
6 determine that out-of-specification findings  
7 were tracked and dealt with, would the product  
8 still be safe?

9 MR. ANDERTON: Objection.

10 You may answer.

11 THE WITNESS: I wouldn't know.  
12 It's not part of my job to determine the  
13 safety of a product or what medical  
14 impact it has.

15 MR. MILLER: I'm going to hand  
16 you what I'm going to mark as  
17 Exhibit 215.

18 (Plaintiff's Exhibit No. 215  
19 was marked for identification.)

20 BY MR. MILLER:

21 Q For the record, this is  
22 Actavis 01425411. Ma'am, I'll represent to  
23 you that this is an e-mail from a Michael  
24 Ponzo dated Monday, January 14th, 2008. And

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1       you can go through that long list of who it's  
2       to. And I don't believe I saw you on here  
3       anywhere. Have you ever seen this e-mail  
4       before?

5           A       (Witness shakes head.)

6           Q       My question is this: Are you  
7       familiar with --

8                   MR. ANDERTON: Did she answer  
9       that question?

10                  MR. MILLER: Well, with a head  
11       nod.

12       BY MR. MILLER:

13           Q       I guess we need to make sure you  
14       actually answer it instead shaking your head.

15           A       Oh, no, I haven't seen this e-mail.

16           Q       You were the senior manager of QA  
17       investigations starting on January 1 of 2008?

18           A       No.

19           Q       No?

20           A       (Witness shakes head.)

21           Q       When did you start?

22           A       Sometime late January 2008.

23           Q       Late January 2008?

24           A       Yeah. I don't recall the specific

1 date.

2 Q Okay. Did you realize or was there  
3 such a thing as a team for open investigation  
4 and performance reports when you took over in  
5 late January of 2008?

6 A What do you mean by "team"?

7 Q What does "team" mean to you?

8 A There are different -- I mean, team  
9 is an organized -- an organized body of, you  
10 know -- basically an organization of people  
11 or, you know, that, you know -- what is a  
12 team?

13 They sit. They, you know -- they're  
14 involved in investigations. And for me, team,  
15 I'm thinking more -- I don't know how you mean  
16 it, whether they're designated, whether  
17 they're, you know, required. There are  
18 different --

19 Q Of all the multiple definitions of  
20 the word "team," I like the one you picked.  
21 Let's use it. Was there a team of open  
22 investigations that you know of in January of  
23 2008?

24 A In January of 2008, I did not know

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1       there was a team at the Little Falls site.

2               Q       When you took over in late January  
3       of 2008, did anyone sit down with you and go  
4       over how many deviations or how many  
5       investigations were open at that time?

6                       MR. ANDERTON:   Objection; asked  
7       and answered.

8                       You may answer.

9                       THE WITNESS:   No one sat with  
10       me in January of 2008 from the Little  
11       Falls site.

12       BY MR. MILLER:

13               Q       Do you think it was important, as  
14       the senior director of quality investigations  
15       group, to know how many investigations were  
16       open at the time that you started your  
17       employment --

18                       MR. ANDERTON:   Objection.

19       BY MR. MILLER:

20               Q       -- at Actavis?

21                       MR. ANDERTON:   Objection.

22                       You may answer.

23                       THE WITNESS:   I started off in  
24       the Actavis Elizabeth site.   So for the

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1 first few weeks, I was being brought up  
2 to speed for only the Actavis Elizabeth  
3 site.

4 BY MR. MILLER:

5 Q Okay. Then --

6 A Then later on in February is when I  
7 started getting the information for the Little  
8 Falls Totowa site.

9 Q In February of 2008 -- take a look  
10 at the attachment. And it appears to be an  
11 Excel spreadsheet of open investigations. Is  
12 this something that you would have  
13 familiarized with or given in February when  
14 you were asked to become aware of open  
15 investigations at Actavis at Little Falls?

16 A Yes.

17 Q So you recall this document,  
18 although it's heavily redacted?

19 MR. ANDERTON: Objection;  
20 mischaracterizes her testimony.

21 THE WITNESS: No.

22 MR. ANDERTON: You may answer.

23 THE WITNESS: I don't know this  
24 particular document.

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1 BY MR. MILLER:

2 Q Well, if we go to Page 3 of 11,  
3 Actavis 01425414, and you see where at the top  
4 it says Open Investigations, are open  
5 investigations something you would have been  
6 concerned with in your job as senior director  
7 of the investigations group?

8 A Senior manager.

9 Q Senior manager. I'm sorry. Senior  
10 manager without a director of the QA  
11 investigations group in February of 2008, is  
12 this a document that you would have been  
13 concerned with?

14 MR. ANDERTON: Objection.

15 You may answer.

16 THE WITNESS: I don't know what  
17 you mean by "concerned," but --

18 BY MR. MILLER:

19 Q I'll stay away from the tough words.

20 But looking at Line 11 here, if you  
21 go down, it says 07-093 with an asterisk.

22 Do you see that, ma'am?

23 A Yes.

24 Q Okay. Is that a number for an

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1 investigation?

2 A Yes.

3 Q Okay. And you're familiar with it?

4 And how does that system work? What does

5 07-093 mean to you?

6 MR. ANDERTON: Objection. You  
7 just asked a question and didn't let her  
8 answer and then moved on to the next  
9 question. So I object to the form. You  
10 said, "Are you familiar with it?" and  
11 then you immediately moved on to the next  
12 question.

13 MR. MILLER: She said "yes."

14 MR. ANDERTON: She didn't  
15 respond. You didn't give her even a  
16 remote chance to respond.

17 MR. MILLER: You might want to  
18 sit over here because you're missing a  
19 lot. She shook her head once and we  
20 fixed that, and a minute ago she just  
21 said "yes."

22 Would you repeat back the  
23 answer and tell me if she said "yes."

24 MR. ANDERTON: She said she --

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1           you asked her if that was a number of an  
2           investigation. She said "yes."

3                   MR. MILLER: Yes.

4                   MR. ANDERTON: Then you said,  
5           "Are you familiar with it?" and then  
6           immediately launched into the next  
7           question without allowing her to respond  
8           to whether she was familiar with it.

9                   MR. MILLER: It was kind of a  
10          rephrasing of the question. All right.

11                   Well, he's already -- I'm not  
12          sure what that was all about. Let's go  
13          back.

14                   MR. ANDERTON: What it's about,  
15          Pete, is your dedication and devotion to  
16          asking imprecise questions and not  
17          allowing her to answer and creating a  
18          misrepresentative record as a result of  
19          that.

20                   MR. MILLER: Very well. Let's  
21          get back to it.

22          BY MR. MILLER:

23                  Q       Explain to me, ma'am, what does  
24          07-093 asterisk indicate to you?

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1           A     I don't recall what the asterisk  
2           represents, but 07 is the year. It represents  
3           the year. And "dash 093" is the sequential  
4           number of the investigation.

5           Q     Okay. So is it fair to say that  
6           that's the 93rd investigation from 2007?

7           A     Correct.

8           Q     Okay. Thank you.

9                     And the next column titled Product,  
10          you agree with me that reads Digoxin Tablets  
11          .125-milligram?

12          A     Correct.

13          Q     Would you have an understanding of  
14          what the OOSN is at the top of the next  
15          column?

16          A     Yes.

17          Q     What is OOSN?

18          A     It's out-of-specification number.

19          Q     Okay. If we go down to the entry in  
20          that field, it says "NA." Do you have an  
21          understanding as to why this particular  
22          inspection would not have an OOSN?

23          A     Yes.

24          Q     Why?

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1           A     Because the investigation wasn't for  
2     an out-of-specification and it didn't result  
3     as a result of an out-of-specification.

4           Q     If we go to the product number,  
5     you're familiar with the product number being  
6     145 of this product?

7           A     If that's what it says.

8           Q     Okay. And you're familiar with the  
9     batch and lot numbering system used at  
10    Actavis; is that a fair statement?

11          A     Yes.

12          Q     Okay. Do you have any specific  
13    memory of Lot or Batch No. 70924A1 of Digitek?

14          A     No.

15          Q     If we go to Deviation Description  
16    and it states: Two tablets of digoxin -- I'm  
17    sorry. My eyes are getting bad.

18                   Two tablets of digoxin tablets  
19    .125-milligram were found with approximately  
20    double the thickness from counter channels  
21    during packaging/filling operation.

22                   Did I read that correctly, ma'am?

23          A     Yes.

24          Q     You've had an extensive work history

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1 in CGMP compliance, and you understand the  
2 meaning of "out of specification"; correct?

3 A Yes.

4 Q Would a tablet that is double the  
5 thickness of what it was supposed to be, is  
6 that out of specification?

7 A It did not meet the requirements. I  
8 think what you need to understand is the way  
9 the out-of-specification number system here at  
10 Actavis Totowa works was this  
11 out-of-specification number were for any  
12 laboratory-generated investigations.

13 Q Should a laboratory-generated  
14 investigation have taken place on this  
15 deviation description?

16 A No.

17 Q Why not?

18 A Because it was an issue that  
19 occurred during the processing of the product.

20 Q Is there a specification for the  
21 proper thickness of a tablet?

22 A I don't know.

23 Q You don't know if a tablet's  
24 supposed to be within a certain range of

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1 thickness?

2 A It depends on what the batch record  
3 says.

4 Q And it says, next column, Initiated  
5 By. And it has D. Joshi?

6 A "Joshi."

7 Q Joshi. What's his title?

8 A I don't know what his title is now.  
9 What it was back then?

10 Q If you know it, sure.

11 A I believe he was the packaging  
12 manager.

13 Q Okay. It says Date Initiated in the  
14 next column. Do you see that? And it's  
15 December 5 of 2007.

16 My question is -- well, actually  
17 let's go on.

18 The next column is Days Open and it  
19 says 40. Now, that 40, you agree with me, is  
20 beyond the required SOP of 30 days?

21 MR. ANDERTON: Objection;  
22 mischaracterizes her testimony and the  
23 document you're referring to.

24 You may answer.

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1 THE WITNESS: The SOP says 30  
2 business days. So I don't know whether  
3 it was 30 business days or...

4 BY MR. MILLER:

5 Q So at the time of this e-mail back  
6 in -- let's see. It's dated January 14th of  
7 2008. It may or may not have been inside the  
8 30 days?

9 A Correct.

10 Q Having read this deviation  
11 description, do you hold any opinion that this  
12 was a part of the reason that Digitek was  
13 recalled?

14 MR. ANDERTON: Objection; asked  
15 and answered.

16 You may answer.

17 THE WITNESS: I indicated to  
18 you I don't know specifically the reason  
19 it was recalled. I was just acting out  
20 on what I was told to do.

21 BY MR. MILLER:

22 Q Very well. I'm going to hand you  
23 what was previously marked Exhibit 130.

24 Ma'am, I'll represent to you this is an

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1 e-mail. It appears to be from you. The "to"  
2 line, for whatever reason, did not print. And  
3 the subject is "Help," dated Tuesday,  
4 February 5th of 2008.

5 Do you recall generating this  
6 e-mail, ma'am?

7 A Yes.

8 Q And down at the bottom, the bottom  
9 half of this e-mail appears to be an e-mail to  
10 you. And, again, I believe it's from Phyllis  
11 Lambridis, but I can't verify that from what's  
12 typed here.

13 And the subject is "Help." And I'll  
14 read that bottom portion.

15 It says: Issue with digoxin in  
16 Riverview. Oil got on tablets during  
17 compression. Needs inspection. Dan doesn't  
18 think an investigation is required. Tony C.  
19 called me because he disagrees. Can you  
20 contact him and open an investigation?  
21 Castellazzo -- am I saying that right?

22 A Yes.

23 Q And that's Anthony; is that right?

24 A Correct.

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1           Q     Okay. And then your response --  
2     actually, let's back up.

3                     Whose decision is it to determine if  
4     an inspection is opened up on something such  
5     as oil was on the tablets during compression?

6           A     Whose -- it could be anyone in  
7     quality.

8           Q     Okay. Well, if such an e-mail --  
9     well, such a decision is out there where two  
10    people are trying to determine if an  
11    inspection needs to be done or not, did you  
12    have the authority, as the senior manager, to  
13    open an investigation yourself?

14          A     You're asking -- there are two  
15    different words. What is it? Is it an  
16    inspection that you're asking about --

17          Q     Yes.

18          A     -- or the investigation?

19          Q     All right. What's the difference  
20    between the two as far as you're concerned?

21          A     Well, an inspection is an activity  
22    that you can basically inspect the tablets.  
23    An investigation is something where it's the  
24    form in how you document the occurrence.

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1           Q     Okay. My question is: Do you have  
2     the authority, as a senior manager of QA  
3     investigations group, to open an investigation  
4     yourself?

5           A     Do I have? Yes.

6           Q     Okay. And then this is your reply,  
7     Tuesday, February 5th. And you would agree  
8     with me that this is within like the first  
9     week that you've taken over, correct, as the  
10    senior manager QA investigation group at  
11    Little Falls?

12          A     Okay.

13          Q     Okay? I mean, do you agree?

14          A     Yes.

15          Q     And you replied back. And your  
16    reply is: Right on it. Sent him an e-mail  
17    requesting details and told Mike to place  
18    product on hold immediately as well as  
19    affected equipment until oil cups are changed  
20    and cleaning is performed. Wow. Looks like  
21    I'm going to ruffle some feathers today.  
22    Excellent.

23                Did I read that correctly, ma'am?

24          A     Yes.

1           Q     Okay. And whose feathers did you  
2 think you were going to ruffle with this  
3 reply?

4           A     Dan. I believe it was Dan.

5           Q     Dan who?

6           A     Bitler.

7           Q     And did your actions, your requested  
8 actions, take place? Did you place the  
9 product on hold?

10          A     I did not. I asked an individual to  
11 place it on hold.

12          Q     And do you know for a fact that it  
13 was or was not placed on hold?

14          A     I don't recall.

15          Q     Did you have the authority, as the  
16 senior manager of quality assurance  
17 investigation group, to put a lot on hold?

18          A     Yes.

19          Q     Were there other occasions where you  
20 exercised your ability to place a lot on hold?

21          A     Yes.

22          Q     What were some of the other  
23 occasions in which you had a product lot put  
24 on hold?

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1 A For varying reasons.

2 Q And was preventing an  
3 out-of-specification -- well, strike that.

4 Was preventing a product that was  
5 not within specifications from entering the  
6 market, was that a reason for putting a  
7 product on hold?

8 A Yeah, as one of the measures,  
9 correct.

10 Q We discussed the last exhibit, the  
11 Lot 70924A that had the tablets that were  
12 approaching double thickness.

13 Do you recall that, ma'am?

14 A Do I recall what?

15 Q That exhibit that I put in front of  
16 you --

17 A Yes.

18 Q -- that discussed that.

19 Did you ever consider putting that  
20 lot on hold?

21 MR. ANDERTON: Objection.

22 THE WITNESS: I --

23 MR. ANDERTON: Objection;

24 mischaracterizes the facts in evidence.

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1                               You may answer.

2                               THE WITNESS: This  
3                               investigation was initiated prior to my  
4                               employment at Actavis.

5 BY MR. MILLER:

6               Q     My question is: Did you ever  
7                   consider putting that lot on hold?

8                               MR. ANDERTON: Objection.

9                               She's already told you the investigation  
10                              was -- occurred before she arrived.

11 BY MR. MILLER:

12              Q     Do you know what the status of that  
13                   lot was -- did you ever look into the status  
14                   of that lot, where it was in the distributing  
15                   cycle, if that is such a thing, once you found  
16                   out about the thickness issue?

17                              MR. ANDERTON: Objection.

18                              You may answer.

19                              Same objection.

20                              THE WITNESS: I don't recall.

21                              It occurred prior to me being there.

22 BY MR. MILLER:

23              Q     I'm going to hand you what was  
24                   previously marked as Exhibit 129. You can

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1 take the time to look at that.

2 Ma'am, if you'd had a chance to  
3 review it, I'd like to ask you a couple of  
4 questions. And my question is relatively  
5 simple, given the length of the document.

6 I'd like to go to the third page,  
7 Actavis 00513871. And it's about a third of  
8 the way down that page. Do you see where your  
9 name starts off, it says Misbah?

10 A Uh-huh.

11 Q Am I saying that right? Is it  
12 "Misbah"?

13 A Yes, Misbah.

14 Q It states: "The following are the  
15 initial details regarding the oil introduction  
16 onto Digoxin tablets during production. Can  
17 QA please provide an investigation number."

18 I don't want to take the time to  
19 read through all that. I'm kind of curious as  
20 the process as to how an occurrence such as  
21 this turns into an investigation and is given  
22 an investigation number, if you know, if you  
23 could walk me through that process.

24 A Okay. Basically, any sort of

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1 departure or any sort of discrepancy that  
2 occurs during the processing of a product,  
3 something that is atypical is typically  
4 documented as an investigation.

5 You want to document what occurred,  
6 how it occurred, why it occurred, any sort of  
7 actions that would be implemented to prevent  
8 recurrence of the situation, and also a way to  
9 document the disposition of the batch after  
10 all of that information has been presented.

11 Q And would your office, you or  
12 someone that reported to you, initiate the  
13 investigation and give it an investigation  
14 number; or was that done prior to the  
15 paperwork arriving at your department?

16 A An investigation can be -- an  
17 investigation number can be generated either  
18 by the QA department or the individual that  
19 was reporting to me, or they can just be  
20 notified of an incident. So once we were  
21 alerted of an issue, we would generate a  
22 number, yes.

23 Q In the case of the lot with the  
24 digoxin with oil spots, do you recall if your

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1 office generated the inspection or was it done  
2 prior to arriving at your office?

3 A The inspection?

4 Q Yes.

5 A The inspection was requested for  
6 this particular one -- I believe we requested  
7 an inspection of the tablets the day we were  
8 notified of the issue.

9 (Plaintiff's Exhibit No. 216  
10 was marked for identification.)

11 BY MR. MILLER:

12 Q I'm going to hand you what I have  
13 marked as Exhibit 216. And this is  
14 Actavis 01420273. And I'll represent to you  
15 it's an e-mail from Mike Ponzio dated Friday,  
16 March 28th, 2008.

17 Do you recall this e-mail, ma'am?

18 A I don't specifically recall it,  
19 but...

20 Q Okay. The subject line is the  
21 Investigation Review Board Meeting Rescheduled  
22 Update.

23 A Okay.

24 Q Do you recall being sent an e-mail

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1 regarding investigation review board meetings?

2 A Yes.

3 Q Okay. Well, what was Michael  
4 Ponzo's title?

5 A I believe he was an investigator for  
6 quality assurance.

7 Q Oh, for quality assurance? Okay.

8 And how does your -- how does that  
9 work? You're the senior manager of quality  
10 assurance investigation group. Did you work  
11 side by side with Michael Ponzo or did you  
12 report to him?

13 A He reported to me.

14 Q He reported to you. Okay.

15 And how did a typical investigation  
16 review board meeting take place? Would he run  
17 the meeting or did you?

18 A Either he or I.

19 Q And everyone -- you can take a  
20 review of who this was to and courtesy-copied.  
21 Would everyone show up at these meetings?

22 A Not everyone.

23 Q How many individuals would you  
24 typically have at a meeting?

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1 A It depends on the week.

2 Q It varied from what to what?

3 A It could vary from -- anywhere from  
4 10 to 20.

5 Q Okay. And these meetings were being  
6 held -- is this something that you generated,  
7 or were they being held prior to your  
8 employment?

9 A They were generated prior to my  
10 employment.

11 Q Okay. But you felt it was as part  
12 of your job title to take over these meetings?  
13 It was something that you were in charge of?

14 A Correct.

15 Q Have you seen these types of  
16 meetings before in your employment in the  
17 pharmaceutical industry?

18 A Yes.

19 Q Did the number of open  
20 investigations at Actavis seem like an  
21 unusually large number to you, or was it what  
22 you were expecting?

23 A What's the question?

24 Q Did the number of open

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1 investigations at Actavis -- I guess we can  
2 take a look at the attachment.

3 But as you recall when you first  
4 started in February 2008, did you think that  
5 there was an unusually large number of open  
6 investigations at Actavis?

7 A As compared to?

8 Q Your other employment.

9 A Not necessarily.

10 Q Was it one of your primary concerns?

11 A Yes.

12 Q And was both the number -- was the  
13 number of open observations a concern?

14 MR. ANDERTON: Objection.

15 You may answer.

16 THE WITNESS: In what regard?

17 Like a concern -- the number of what?

18 Observations?

19 BY MR. MILLER:

20 Q Yes. Were you -- was part of your  
21 task, as the senior manager QA investigations  
22 group, were you attempting to reduce the  
23 number of open investigations?

24 A Yes.

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1           Q     Were you attempting to reduce the  
2     amount of days it took to close an  
3     investigation?

4           A     Yes, as part of continuous  
5     improvement.

6           Q     If we go to -- we'll take a look at  
7     the attachment titled "Open Investigations"  
8     and go to Page 7 of 21. And take a look at --  
9     the first column has the numbers. And go down  
10    to No. 30. And you see that that entry is  
11    08-046?

12          A     Okay.

13          Q     Would you agree that that is the  
14    46th investigation of 2008?

15          A     Correct.

16          Q     And it has, let's see, digoxin  
17    tablets, .125. Again, the OOSN is NA. If we  
18    go across to the column that's titled  
19    "Deviation Description," it says: "T zero  
20    stability testing was not conducted when CRT  
21    stability study was initiated."

22                     And it has a responsible party.

23                     How would you, as the senior manager  
24    of QA investigations group, ensure that these

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1 investigations were moved along and closed in  
2 a timely fashion?

3 A Well, part of it was having these  
4 weekly meetings to discuss what the status of  
5 the investigation was, what information was  
6 required to try to bring it to closure.

7 Q Other than the input you received  
8 during the meetings, would you actively go out  
9 and discuss with the different departments  
10 what the status was?

11 A Yes.

12 Q Where was your physical office?

13 A I had two.

14 Q And they were where?

15 A One was in Elizabeth. The other one  
16 was in Little Falls.

17 Q How much time did you spend in --  
18 how did you split your time amongst the two  
19 offices?

20 A For the majority, I spent three days  
21 in Little Falls and two days in Elizabeth.

22 Q Okay.

23 A However, just -- there were points  
24 where I think I spent most of the week in the

1 beginning in Little Falls. I would do four to  
2 five days.

3 Q If we go to Page 9 of 21 of this  
4 document titled "Open Investigations," and we  
5 go down to Line 35, and it's -- this would be  
6 08-051, the 51st investigation of 2008, and we  
7 go across to Deviation Description, it says:  
8 "Employees involved in the execution of  
9 validation protocols were not trained." And  
10 responsible party is the tech services, and  
11 then date initiated.

12 As the senior manager of quality  
13 assurance investigations group, were you  
14 responsible for initiating such an  
15 investigation, or would a finding like this be  
16 brought to your attention?

17 A A finding like this would be brought  
18 to my attention.

19 Q And then what was your  
20 responsibility to ensure that such training  
21 took place?

22 A I'm sorry?

23 Q Were you responsible for ensuring  
24 that the employees involved in the execution

1 of validation protocols were trained; or did  
2 you tell the office that needed to do the  
3 training, hey, these folks need to be trained?

4 A Right; the department that was  
5 responsible would have to train.

6 Q I'm going to hand you what's been  
7 marked Exhibit 141. Ma'am, this document is  
8 titled "Investigation No. 08-060."

9 Have you seen this document before?

10 A I don't recall. I'm sure I have. I  
11 just don't recall the specifics.

12 Q I understand. Is this the form that  
13 a final investigation report takes?

14 A No.

15 Q Okay. What would be the difference  
16 between what I hold in my hand as  
17 Investigation No. 08-06 and what the final  
18 report would look like?

19 A The final report would have a lot  
20 more information. It would discuss the event  
21 in more detail. It would indicate what  
22 possible causes could have attributed to the  
23 discrepancy, what actions were taken, any sort  
24 of -- basically all of the investigational

1 activities that were performed to identify a  
2 root cause, if possible.

3 Q And then how would that final report  
4 be maintained?

5 A As -- what do you mean?

6 Q Well, there's a final paper report.  
7 You had a discussion we addressed during the  
8 inspection regarding paper reports or  
9 TrackWise.

10 And my question is: If it's a paper  
11 reporting system that was being utilized in  
12 Little Falls at this time -- is that correct?

13 A Correct.

14 Q -- where was that paper report  
15 actually maintained when it was finalized?

16 A It was maintained in the files.

17 Q In the files in?

18 A In our area.

19 Q In your office or an office that you  
20 were in charge of?

21 A An office that was designated for  
22 investigations.

23 Q And you were in control of that  
24 office; correct?

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1 A Yes.

2 Q Were they scanned in so that you  
3 could call them up electronically and kept in  
4 a file?

5 A Some of them were scanned just for  
6 ease either because we needed to send the  
7 report, a copy of the report to a department  
8 that needed it or, you know, if someone  
9 required a copy of it.

10 Q Some were scanned -- I'm sorry. I  
11 didn't mean to step on you.

12 Some were scanned but not all?

13 A Correct.

14 Q This particular document that we're  
15 looking at, Plaintiff's Document 141, would  
16 this be -- would you categorize this as a  
17 draft investigation report or preliminary  
18 report? How would such a document be --

19 A I believe -- I believe this one is  
20 the initial notification of a discrepancy that  
21 occurred. So it was basically something like  
22 this would be sent to us to indicate, you  
23 know, hey, this is an issue; it was observed  
24 by this individual on this date; what was the

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1 initial -- what the discrepancy was; how it  
2 was discovered; the basics.

3 Q And it was product digoxin tablets  
4 .125 milligrams. And then it has a control  
5 number 80228A1.

6 Are you familiar with what a control  
7 number would be on an investigation?

8 A In this case, it would represent the  
9 lot number.

10 Q Okay. Fill size, would that be the  
11 size of the lot? Are you familiar with what  
12 the fill size is?

13 A I believe the fill size is what it  
14 was being packaged into, so the packaging  
15 configuration.

16 Q Okay. And if we cut to the chase  
17 here and talk about what discrepancy was  
18 found, it states: "He found 17 tablets with  
19 higher weight out of 30 tablets."

20 Do you recall that particular issue  
21 with digoxin in the time frame early April of  
22 2008?

23 A Not the specifics of it, but I  
24 recall in general.

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1           Q     And this report of the incident,  
2     would it be submitted to you to generate the  
3     investigation?

4           A     Either to me or someone in my group.

5           Q     Okay. Do you recall working on this  
6     specific investigation?

7           A     I believe -- I believe I did. I  
8     think I might have reviewed it and approved  
9     it. I'm not quite sure.

10          Q     It says Preliminary Root Cause at  
11     the bottom of the document, but it goes on to  
12     say that the root cause, here at the last  
13     sentence of this paragraph: "Root cause of  
14     this deviation is to be determined at  
15     manufacturing stage."

16                     Did I read that correct, ma'am?

17          A     Yes.

18          Q     Would you take any steps, as the  
19     senior manager of quality assurance  
20     investigation group, to have laboratory  
21     testing of any type done on a lot in which  
22     tablets were found to be higher weight than  
23     they're supposed to be?

24          A     I'm sorry. Ask that again.

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1 Q Certainly. Is there -- would you,  
2 as part of the investigation, request or --  
3 yeah, request that laboratory do testing on a  
4 lot that has out-of-weight specification  
5 tablets?

6 A It depends on what the issue was.  
7 I -- it has to come on an individual incident  
8 basis. I would need more information before I  
9 commit to whether I would request that  
10 information or not.

11 Q Okay. So based on the finding that  
12 17 tablets were higher weight than they were  
13 supposed to be, that's not enough information  
14 to say we need to do some laboratory  
15 testing --

16 A No.

17 Q -- on this lot?

18 A No.

19 Q Does 17 tablets that are higher  
20 weight than what is specified, does that raise  
21 to the level of a field alert?

22 A No.

23 Q Why?

24 A A field alert is generated for

1 distributed product, product that is already  
2 in the market.

3 Q Product that's already been  
4 distributed?

5 A Correct.

6 Q Well, when we looked at the open  
7 investigation on the lot that had tablets  
8 approaching double thickness that came out in  
9 January, you indicated that one of the reasons  
10 you didn't consider a field alert was because  
11 it happened before you were there?

12 Do you recall that?

13 MR. ANDERTON: Objection;  
14 mischaracterizes her testimony. She  
15 didn't say she didn't consider a field  
16 alert. She said she wasn't involved  
17 because it happened before she was there.

18 BY MR. MILLER:

19 Q Being the senior manager in charge  
20 of quality assurance investigation group, you  
21 were aware that there were -- that there was a  
22 lot in November of 2007 that had a thickness  
23 issue; is that correct?

24 A In November?

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1 Q Yes.

2 A Which one are you speaking of?

3 Q The 70924A. If you go back to  
4 Exhibit 216, the attachment of, and if you  
5 look at Page 3 of 11 -- and I realize you  
6 weren't there when the lot was manufactured.  
7 I guess the investigation was initiated in  
8 December of '07, a month prior to your arrival  
9 at Actavis. But once you were employed at  
10 Actavis, you became aware of this lot; is that  
11 correct?

12 A Correct.

13 Q And given that you -- and you were  
14 aware that this was a thickness issue with  
15 this lot; is that correct?

16 A Okay. Yes.

17 Q Okay. Did you ever become familiar  
18 with what the root cause for that thickness  
19 issue was?

20 MR. ANDERTON: Objection; asked  
21 and answered several times now.

22 BY MR. MILLER:

23 Q It's okay to answer.

24 MR. ANDERTON: You may answer.

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1 THE WITNESS: For this  
2 particular investigation, I don't recall.  
3 It would -- I would have to look at the  
4 investigation report to see what was  
5 determined to be the cause.

6 BY MR. MILLER:

7 Q But you agree that there was a  
8 thickness issue just prior to your arrival at  
9 Actavis?

10 A Okay. Yes.

11 Q You agree with that?

12 A Okay. Yes.

13 Q And then two months after you've  
14 taken over this job, on April 1st of 2008, you  
15 agree that there's another lot with a  
16 thickness issue or a weight issue; is that  
17 correct?

18 A There's an -- yeah, there was a  
19 notification of a weight issue, correct.

20 Q And part of your job is to track out  
21 of -- open investigations; is that correct?

22 A Yes.

23 Q And by tracking, to see if issues  
24 are repeating; is that correct?

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1 A Yes.

2 Q And would these -- would you agree  
3 that you have two out-of-specification lots  
4 with Actavis; is this something that would  
5 raise your level of concern regarding tracking  
6 this product?

7 A To a certain extent, it would. We  
8 would investigate the same way. We would have  
9 to try to determine what the root cause was to  
10 further track it and make sure that it was  
11 tracked properly.

12 Q Would this be a reason for the  
13 senior manager of QA investigation group to go  
14 back and see if there were any other issues  
15 with thickness or weight with this particular  
16 product?

17 A Yes.

18 Q Do you recall doing such an  
19 investigation?

20 A An investigation specifically to  
21 review historical?

22 Q Historical information to see if  
23 there were other lots that had issues with  
24 out-of-specification weight and thickness for

1 Digitek.

2 A I may have. Again, I need to see  
3 the actual report to determine what actions I  
4 took for this specific case.

5 Q But as you sit here today, you have  
6 no memory of going back and doing a historical  
7 report and to determine if there were any past  
8 lots that had issues?

9 A I don't recall what I did at that  
10 point. But, again, I don't know the  
11 specifics. I'd have to see the report to see  
12 what I did.

13 Q And when you say you'd have to see  
14 the report, that would be the final  
15 investigation --

16 A Correct.

17 Q -- of this?

18 And if you determined to do a  
19 historical search on other lots, it would be  
20 in that final investigation?

21 A Yes.

22 Q I'm going to hand you what was  
23 previously marked as 142.

24 Ma'am, you have had time to review

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1       that. Do you agree that it's a conversation  
2       regarding the lot we've discussed, that being  
3       80202 alpha?

4                       MR. ANDERTON: Objection. When  
5       was there a discussion of that lot?

6                       MR. MILLER: Perhaps it's a  
7       different lot.

8       BY MR. MILLER:

9               Q       Ma'am, if you go to Page -- these  
10       numbers are all cut off. It's the fourth from  
11       the back that states: Subject  
12       Investigation 08-60.

13              A       I'm sorry. Which one are we --

14              Q       It's about the third or fourth page  
15       from the back. And it starts -- has the cc on  
16       the top of it. Actually, it's exactly four  
17       pages from the back, if you go to the last  
18       page and count back four.

19              A       Okay.

20              Q       And if you recall, previously we  
21       were discussing Plaintiff's Exhibit 141 that  
22       discussed Investigation 08-060.

23                      Do you recall that?

24              A       Yes.

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1 Q And this subject line here is  
2 Investigation 08-060.

3 Do you see that, ma'am --

4 A Yes.

5 Q -- on the exhibit?

6 And it discusses the same issue,  
7 would you agree, and that is the  
8 .125-milligram tablets were found above weight  
9 specification?

10 Do you agree with that?

11 A Yes.

12 Q And if we go to the very first page,  
13 we go back to the very first page of  
14 Exhibit 142, and it's from Dan Bitler. And  
15 although the "to" line is not there,  
16 intuitively it's to you because it starts out  
17 "Misbah."

18 Do you agree with that?

19 A Yes.

20 Q And it's a response to your question  
21 at the bottom, which says: Has Batch 80202  
22 alpha been released?

23 Am I reading that correctly?

24 A Yes.

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1           Q     And the answer to you is: Misbah,  
2     yes, Batch 80202A was released and shipped to  
3     Mylan Labs on Monday, March 31st, 2008. I  
4     have contacted Mylan, have discussed the  
5     situation with them, and they are putting the  
6     batch on hold.

7                     Do you remember having this e-mail  
8     exchange with Dan Bitler?

9           A     Obviously I had it.

10          Q     Fair enough. Obviously you had it.  
11     I'm just wondering if you remember.

12          A     Not specifically but...

13          Q     Okay. Would this be -- do you  
14     recall if that lot or batch was ever released?

15          A     Released by who?

16          Q     By Mylan.

17          A     I don't know. I don't recall.

18          Q     Did you do any follow-up beyond this  
19     on this lot whatsoever?

20          A     I don't recall.

21          Q     Do you recall out-of-specification  
22     weight or thickness becoming an issue in early  
23     April for Digitek?

24          A     I'm sorry. Can you repeat the

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1 question?

2 Q Do you recall out-of-specification  
3 weight or thickness becoming an issue with the  
4 product Digitek in early April 2008?

5 A What do you mean by "issue"?

6 Q Was that one of the things that you  
7 were focused on in your day-to-day routine as  
8 senior manager of quality assurance  
9 investigation group?

10 A How -- I'm not sure how you mean  
11 "focused on." It was something that I had  
12 oversight of.

13 Q And what does "oversight" mean to  
14 you?

15 A It was under my radar. I kept -- I  
16 had an oversight in regards to I was assessing  
17 the status of it, what -- you know, where we  
18 were in trying to resolve the investigation  
19 related to these particular cases.

20 Q Potentially, could a field alert  
21 come from any other office than yourself, or  
22 would it typically come from you and your  
23 department?

24 A As I indicated to you, it was not my

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1 responsibility when I was first hired. So  
2 there were cases when it would come from  
3 individuals other than myself.

4 Q When did it become your  
5 responsibility?

6 A Officially it became my  
7 responsibility, I think, sometime in June.

8 MR. MILLER: Three minutes.

9 Let's take a break.

10 MR. ANDERTON: Okay.

11 THE VIDEOGRAPHER: This  
12 completes Videotape 1. Off the record at  
13 11:07 a.m.

14 (Short recess.)

15 THE VIDEOGRAPHER: This is  
16 Videotape No. 2. Back on the record at  
17 11:16 a.m.

18 BY MR. MILLER:

19 Q Ma'am, just prior to the break, we  
20 were discussing Investigation 08-060.

21 Do you recall that?

22 A Yes.

23 Q For that topic, I'm going to hand  
24 you what was previously marked Exhibit 145.

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1 Ready?

2 A Yes.

3 Q Take a look at the second-to-last  
4 page, Actavis 0300112. And about -- it's  
5 difficult to read the format the way this came  
6 out. But going down about two thirds down the  
7 page, it says: Subject: Regarding  
8 Investigation 08-060, where it says "Please  
9 consider."

10 Do you see that ma'am?

11 A Yes.

12 Q "Please consider what other batches  
13 in campaign may be impacted so we can get  
14 these on hold if applicable."

15 Who would Michael be? Do you have  
16 an understanding of who electronically signed  
17 this?

18 A What are you asking? So we can  
19 get --

20 Q Yes.

21 A It's not signed "Michael." That's  
22 the next e-mail exchange.

23 Q Well, that's what I'm trying to  
24 determine actually. You don't think the word

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1 "Michael" is the ending of that text?

2 A No. Because Michael is the next  
3 e-mail, isn't it? It's the start because it's  
4 Michael Ponzo. So isn't that the next e-mail  
5 communication?

6 Q I'll be quite honest; I'm not sure.  
7 Would you agree with me this e-mail was  
8 generated by Dilip M.?

9 MR. ANDERTON: Which e-mail?

10 THE WITNESS: Which e-mail?

11 BY MR. MILLER:

12 Q The one I just read.

13 A No. It actually says from Tony  
14 Delicato.

15 Q Well, you got a better eye on this  
16 than I do. Okay. I'll go with that. From  
17 Tony Delicato.

18 And you agree with me that the  
19 subject of this e-mail is to determine if  
20 other batches in the campaign may be impacted,  
21 and you agree that that's regarding  
22 Investigation 08-060?

23 A Correct.

24 Q And does Tony Delicato -- what's his

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1 job title?

2 A I believe at this time he was the  
3 director of quality assurance. I don't know  
4 whether it was for all of New Jersey or  
5 whether it was just specific to Elizabeth.

6 Q As the senior manager of quality  
7 insurance for investigation group, do you  
8 report to him?

9 A I did report to him, yes.

10 Q Okay. He is looking for information  
11 regarding the campaign. Do you understand  
12 what it means by "campaign"?

13 A Yes.

14 Q And what does "campaign" mean?

15 A "Campaign" means batches that are  
16 produced together, that they're processed  
17 subsequent to each other.

18 Q Okay. And looking into if an  
19 out-of-specification issue affects a campaign,  
20 is that something your department would do or  
21 something that the manufacturing QA would take  
22 care of?

23 A There's no such thing as  
24 manufacturing QA.

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1 Q Then who is charged with determining  
2 if the other batches in a campaign are  
3 affected by such an issue that was outlined in  
4 Investigation 08-060?

5 A That would be quality assurance.

6 Q Quality assurance investigation  
7 group?

8 A As well as overall quality  
9 assurance. Just so you know, quality  
10 assurance, it's an overall department. There  
11 are groups within quality assurance.

12 Q And I'm trying to determine which  
13 group -- is it your group that is charged with  
14 determining if other campaigns are impacted?

15 A We can do that as well as quality  
16 assurance in general. It can be anyone in  
17 quality assurance.

18 Q But then there's another layer to  
19 that, would you agree, that just not are the  
20 batches in that campaign affected, but you  
21 also want to see if it's an issue historically  
22 to determine if that problem with that lot  
23 that was identified in the investigation has  
24 happened over time. Do you agree?

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1           A     Again, for this particular -- it  
2     depends. It's almost a twofold step. You  
3     have to determine what the issue is and try to  
4     assess what lots were impacted. There may  
5     have been changes so, you know, that limit  
6     when whatever the cause of this impacted the  
7     batches. So...

8           Q     And an important step, would you  
9     agree, would be determining the root cause?

10          A     If you can determine it, yes.

11          Q     You've had the opportunity to review  
12     this e-mail. And going to the second page,  
13     300111, and it's an e-mail that appears to be  
14     from Mike to you. And what Mike would that  
15     be?

16          A     I'm sorry?

17          Q     Do you know who the Mike is in the  
18     very -- in the page you're on, it says  
19     "Misbah" and then there's text and at the end  
20     it's "Mike." Do you know who Mike is?

21          A     It would appear to be Michael Ponzo.

22          Q     All right. So Michael Ponzo states:  
23     "Misbah, I'm sorry. I have to get out of the  
24     habit of getting into everything too. My

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1 problem is, here, that is what I'm used to.  
2 No one went the extra yard when I started, so  
3 I had to get into everything. I understand  
4 why you want ea department to start doing  
5 their own work, they are the experts and they  
6 should be held accountable. I'll learn, and  
7 keep reminding me when I go beyond my  
8 boundaries. Mike."

9 Did you understand what Mike was  
10 trying to get across to you here?

11 A At the time I'm sure I did. Now I  
12 don't recall.

13 Q Was there a sense in early April of  
14 2008 that there was finger-pointing, for lack  
15 of a better term, at the different departments  
16 when it came to investigations?

17 MR. ANDERTON: Objection.

18 You may answer.

19 THE WITNESS: I don't believe  
20 so.

21 BY MR. MILLER:

22 Q Well, if we go to the next page, the  
23 way I read this e-mail, it looks like an  
24 e-mail from you at the very bottom to Kanisha

1 Jones?

2 A Are we on the first page?

3 Q Yes.

4 A Yes.

5 Q Is that an e-mail from you to  
6 Kanesha Jones the second half or the bottom  
7 half of the page that the text is just  
8 "Shhhh"?

9 A Yes.

10 Q Do you recall why you had typed  
11 that?

12 A I don't recall.

13 Q The next e-mail above that is to  
14 you. And I'm assuming it's from Kanesha  
15 Jones. Who was Kanesha Jones?

16 A Kanesha was also an investigator  
17 that worked for me.

18 Q And what is LMAO?

19 A What does it stand for?

20 Q Yes.

21 A I'm assuming it stands for "laughing  
22 my ass off."

23 Q It says: "I guess it was evident  
24 that you were pissed off."

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1 Do you recall having an e-mail  
2 conversation with Kanisha Jones about being  
3 upset over this exchange?

4 A Well, I mean, this is the e-mail,  
5 but I don't recall what occurred.

6 MR. MILLER: Fair enough.

7 I'm going to hand you what I'm  
8 going to mark as Exhibit 217, if you  
9 would take the opportunity to look at  
10 that.

11 (Plaintiff's Exhibit No. 217  
12 was marked for identification.)

13 BY MR. MILLER:

14 Q Have you had a chance to review  
15 that, ma'am?

16 A Yes.

17 Q Okay. My question to you is --  
18 we'll take a look at this document. You agree  
19 this is an e-mail from you?

20 A Yes.

21 Q Dated Tuesday, April 15th, 2008.  
22 The subject line is "List by Product." And  
23 there's an attachment that's dated  
24 5 September 2007: Present Investigations by

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1 Product.xls.

2 Did I read that correctly?

3 A Well, it's basically investigations  
4 from September 5th, '07, to --

5 Q Forward?

6 A -- to that present time.

7 Q All right, ma'am. Do you recall --  
8 well, actually I'll go through the contents  
9 real quick. It states: She's gone through  
10 both. There should be no more surprises.

11 And it's forwarded by you. Did you  
12 recall generating this e-mail after you had an  
13 opportunity to review it?

14 A I don't -- I mean, I generated it;  
15 but, again, I don't recall.

16 Q Do you recall if it was generated  
17 for the investigation that was going on with  
18 the FDA during the month of April 2008?

19 MR. ANDERTON: You mean the  
20 inspection?

21 MR. MILLER: Thank you.  
22 Inspection.

23 THE WITNESS: Was it? Excuse  
24 me. Can you repeat the question?

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1 BY MR. MILLER:

2 Q Was that list forwarded in response  
3 to a request regarding the inspection that was  
4 going on in 2008?

5 A It appears to be.

6 Q And if we take a look at the  
7 attachment, you agree with me that this is a  
8 document that lists the investigations by  
9 product at Actavis, specifically Little Falls?

10 A Correct.

11 Q And if we go down to page in the  
12 lower right corner Actavis 299886, and do you  
13 see where the product identified is Digitek?

14 A Yes.

15 Q And these were investigations that  
16 your department was handling at the time; is  
17 that correct?

18 A Monitoring?

19 Q Yes.

20 A Yes.

21 Q It says: Two tablets -- I'm going  
22 to go with the first entry after Digitek and  
23 the left side investigation number was 07-093.

24 And if we go to the reason for

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1 investigation, it says: Two tablets of  
2 digoxin tablets, .125-milligram, were found  
3 with approximately double the thickness from  
4 counter channels during packaging/filing  
5 operation.

6 Did I read that correctly?

7 A "Filling operation."

8 Q Thank you. And here we have  
9 Status: Closed.

10 Were you involved in the closing of  
11 that investigation?

12 MR. ANDERTON: Objection; asked  
13 and answered several times.

14 You may answer.

15 THE WITNESS: I don't think so  
16 because I wasn't at the Little Falls site  
17 during that time it was closed.

18 BY MR. MILLER:

19 Q Who would have been responsible for  
20 closing an investigation the date this was  
21 closed? And the date off of this is  
22 1/25/2008.

23 A I would think it would either be Dan  
24 Bitler or Scott Talbot.

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1 Q If we go on to the next Digitek open  
2 investigation, that would be 08-11 --

3 MR. ANDERTON: Objection;  
4 mischaracterizes the document. I don't  
5 know why you're calling these open  
6 investigations.

7 MR. MILLER: Okay. I think  
8 you're correct. Strike that. I'll ask  
9 the question again.

10 BY MR. MILLER:

11 Q If we go back to the first page of  
12 this exhibit, the attachment is: Present  
13 Investigations by product.

14 Is there a distinction with an  
15 attachment titled "Present Investigations" if  
16 they're open or closed?

17 A I'm sorry?

18 Q What do you mean by "Present  
19 Investigations" in your title of your  
20 attachment in your e-mail?

21 A I don't believe I generated --  
22 again, this is a forward. So the attachment  
23 was generated for me by someone, and it was  
24 forwarded to me.

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1 Q Okay. As it was forwarded to you,  
2 did you have an understanding as to what  
3 "Present Investigations" meant?

4 A Well, it --

5 MR. ANDERTON: I think you're  
6 misreading the document --

7 THE WITNESS: Right.

8 MR. ANDERTON: -- Pete.

9 But go ahead.

10 I think it's investigations by  
11 product September 5, '07, to the present.

12 THE WITNESS: Correct.

13 MR. MILLER: Oh. I stand  
14 corrected. The light just came on.  
15 Sorry about that.

16 MR. ANDERTON: She said that in  
17 her earlier testimony.

18 MR. MILLER: Sometimes you have  
19 to listen and speak and that can be a  
20 difficult thing. Okay. Fair enough.

21 BY MR. MILLER:

22 Q Let's go back to the second entry,  
23 Digitek, and it's investigation number 08-011.

24 Do you see that?

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1 A Yes.

2 Q And this investigation closed, the  
3 very last column on the right, March 3rd of  
4 2008. Now, you were the senior manager of the  
5 investigation group at that time; is that  
6 correct?

7 A Correct.

8 Q And this investigation, the reason  
9 for the investigation was one stainless steel  
10 screw was found in the tablet well of the  
11 BOSS-PACK filling machine during packaging.

12 Do you recall that particular  
13 investigation?

14 A I recall the incident, yes.

15 Q Okay. And do you recall doing  
16 research on that incident to determine if  
17 there was a history of that type of deviation?

18 A I would actually need to see that  
19 report in order to answer that question.

20 Q How often do you go back and  
21 historically look at deviations to determine  
22 if there's a trend? How often would that have  
23 taken place in your employment in the QA  
24 investigation group in January through April

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1 of 2008?

2 A That would be determined by the  
3 procedure.

4 Q No. In your memory, how often do  
5 you recall doing that? Is that something you  
6 did daily? Weekly?

7 A To what? Perform a historical  
8 review?

9 Q Yes.

10 A Typically, that should be done for  
11 every investigation.

12 Q The next investigation number is  
13 08-017 for Digitek. And this one was also  
14 closed early March of 2008. The reason for  
15 investigation: During compression of  
16 Drums No. 5 and No. 6, the compressor operator  
17 observed oil spots on some of the in-process  
18 tablets.

19 My question is: Does that  
20 investigation stand out in your mind as you  
21 sit here today? Do you have any memory of  
22 that investigation?

23 A Well, it was, I believe, the  
24 investigation that was discussed previously.

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1           Q     I believe you're correct. Does this  
2 jog your memory at all?

3           A     In regards to?

4           Q     Having any memory of this  
5 investigation other than what's written here.

6           A     I don't recall the specifics of it.  
7 I would have to see the document.

8           Q     But your earlier testimony, you felt  
9 that all investigations warranted a historical  
10 inspection of previous lots, so you believe  
11 this would rise to that level as well?

12          A     Yes. But, again, let me clarify.  
13 It should be done historically; but once an  
14 assignable cause is determined, if you -- it  
15 should be assessed what the root cause of the  
16 situation was, and then you can perform also a  
17 historical review to see if that cause  
18 occurred previously and was the reason for the  
19 discrepancy.

20          Q     I understand. And the inspections  
21 we reviewed thus far on this exhibit, you  
22 agree as it's labeled here, were Digitek  
23 .125 milligrams; correct?

24          A     The investigations? Correct.

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1 Q And if we go down to the next entry  
2 or line, it's titled "Digitek (digoxin  
3 tablets)" .25 milligrams." Those, you  
4 understand, are the two different size options  
5 or strength options that were produced by  
6 Actavis?

7 A Correct.

8 Q And if we go down to the third  
9 entry, Exhibit 08-030, and this is another  
10 inspection that was closed March 7th of 2008.  
11 And if we read the reason for investigation,  
12 it says: Operator noticed tablets that were  
13 thinner than a typical tablet during the  
14 inspection of Drum No. 2.

15 Did I read that correctly?

16 A Correct.

17 Q My question is to you, as the senior  
18 manager of quality assurance in the  
19 investigation group: If you see thickness  
20 issues in a product, albeit the two different  
21 strengths of the product, does that become a  
22 concern or do you keep it separated because  
23 it's two different strengths?

24 A It would -- again, it would -- I

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1 would have to look at the overall issue and  
2 the specifics of it to determine whether I was  
3 going to correlate them or not.

4 Q Ma'am, going back to Exhibit 141,  
5 which was Investigation No. 08-060, you recall  
6 this was 17 tablets with a higher weight? Do  
7 you recall us discussing that?

8 A Yes.

9 Q If this is a list of investigations  
10 from September 7 to present, which I finally  
11 sorted out, my question would be: How would  
12 it come to be that that investigation wouldn't  
13 make this list?

14 A Again, I -- I can't tell you that  
15 because I didn't generate the list. But,  
16 again, what I indicated to you earlier, one of  
17 the things that had been discussed with the  
18 investigator was the efficiency of going --  
19 you know, utilizing a paper-based system to  
20 TrackWise.

21 So a lot of it was information,  
22 again, the efficiency, how quickly we were  
23 able to present information, how it would be  
24 sorted, how it would be tracked. So perhaps

1 that was the issue that caused it not to  
2 appear on this, how it was categorized.

3 Q Do you see any reason why  
4 investigation 08-060 should not have been  
5 included on this attachment that we're reading  
6 now?

7 A Looking at the information I have  
8 currently, I don't see why it would have been  
9 excluded.

10 Q Well, given that there were higher  
11 weight tablets in Investigation 08-060, and  
12 that was in a .125-milligram tablet, and  
13 there's .125-milligram tablets that we  
14 addressed in Investigation 07-093 that were  
15 approximately double the thickness, and then  
16 digoxin .25-milligram we see  
17 Investigation 08-030 where the operator  
18 noticed tablets that were thinner than a  
19 typical tablet; are these three findings  
20 enough for a senior manager of a quality  
21 investigation group to determine that a  
22 historical review needs to be done of other  
23 lots?

24 A Perhaps.

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1 Q Do you have a memory of doing just  
2 that?

3 A I don't recall.

4 Q But, again, you believe that  
5 information would be found in the final  
6 investigation report?

7 A Perhaps.

8 MR. MILLER: I'm going to hand  
9 you what I'm going to mark as  
10 Exhibit 218.

11 (Plaintiff's Exhibit No. 218  
12 was marked for identification.)

13 MR. ANDERTON: I'm sorry. What  
14 number? 218?

15 MR. MILLER: Yes.

16 MR. ANDERTON: Thank you.

17 BY MR. MILLER:

18 Q And, ma'am, for the record, this is  
19 Actavis Document 01265670. And I'll represent  
20 to you that it was produced to us. And you  
21 agree that it's an e-mail from you?

22 A Correct.

23 Q It was be sent Thursday, April 24th,  
24 2008, to Tony Delicato, and subject regarding

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1 PR12181.

2 Does that mean anything to you now  
3 as you sit here?

4 A No. It's just an investigation  
5 number.

6 Q And how does that investigation  
7 number work? We talked earlier about the ones  
8 that identified the year and the sequential  
9 number of the investigation. What's the  
10 breakdown of this type of investigation  
11 number?

12 A Well, this one is generated  
13 automatically by the TrackWise system, which  
14 was in place in Elizabeth. So this is  
15 pertaining to an Elizabeth investigation.

16 Q I may have a different view on this  
17 than you. But it looks like at the bottom  
18 it's the original e-mail that you're replying  
19 to, and it's from Tony Delicato to you?

20 A Correct.

21 Q And it states: Can you dig into the  
22 details on this one and ensure QC has looked  
23 at everything, reviewed method, et cetera.  
24 I'm concerned because we have a history of

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1 high assay/dissolution results, and we may  
2 need to put MF on hold pending further  
3 evaluation. A campaign is in process, and the  
4 next one is scheduled in two weeks. We may  
5 want to do this prior to FDA questioning.  
6 Obviously this is high priority.

7 Did I read that correctly?

8 A Correct.

9 MR. ANDERTON: Objection. No,  
10 you didn't.

11 But go ahead. You may answer.

12 BY MR. MILLER:

13 Q Would you agree that Tony Delicato  
14 is requesting your review of a product that  
15 has a history of out-of-specifications and  
16 he's asking for your review of that product?

17 MR. ANDERTON: Objection;  
18 again, mischaracterizes the document.

19 You may answer.

20 THE WITNESS: It doesn't say  
21 anything about out of specification.

22 BY MR. MILLER:

23 Q Okay. Is a -- what is an  
24 assay/dissolution? If I'm saying that right.

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1 A They're analyses.

2 Q If that analyses is not within  
3 specifications, would that be labeled an  
4 out -- an OOS within the company?

5 A If it's not within the  
6 specifications?

7 Q Right.

8 A Then it would be an  
9 out-of-specification.

10 Q But you're saying that it could be  
11 high but not be outside of the specifications?

12 A Correct.

13 Q And your response is: No problem.  
14 Just need to get a press release for digoxin  
15 out within 45 minutes per Robert Wessman, and  
16 then I'll look into this issue.

17 Were you communicating directly with  
18 Robert Wessman regarding a press release for  
19 digoxin around the time frame April 24th,  
20 2008?

21 A No, I was not directly dealing with  
22 him.

23 Q Who is Robert Wessman?

24 A He was, I believe, the president of

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1 Actavis.

2 Q And how did his request that you  
3 generate a press release for digoxin, how did  
4 that request get to you?

5 A The request to issue a press release  
6 actually did not come from Robert Wessman, but  
7 the time frame came from him.

8 Q Okay. What did you mean by had to  
9 be out within 45 minutes per Robert Wessman?

10 A He requested that we issue a press  
11 release within 45 minutes.

12 Q And who instructed you to generate  
13 that press release?

14 A I believe it was Phyllis Lambridis.

15 Q And was that a press release  
16 regarding a potential recall?

17 A I believe so.

18 Q And did you, in fact, draft the  
19 press release?

20 A I believe so. I think -- yeah, I  
21 did.

22 Q And is the intent of a press release  
23 to get information out to the public?

24 A Yes.

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1 Q Okay. Is there a safety aspect to  
2 that?

3 A Perhaps.

4 Q It could include potential health  
5 risks?

6 A It may include that.

7 Q And how do you get -- as someone  
8 who's drafting a press release for a drug  
9 recall, what steps do you take in order to get  
10 medical information to enter in the press  
11 release?

12 A Typically I would have to contact  
13 the medical affairs department.

14 Q Okay. Do you have a memory of  
15 putting together the press release for  
16 Digitek?

17 A Yes.

18 Q What memory do you have regarding  
19 gathering the medical information?

20 A None specifically. I know I had to  
21 draft the press release, but that's pretty  
22 much it.

23 Q Okay. Well, then I'll back up. The  
24 question before that I asked you if you have a

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1 memory of putting that together, what memory  
2 do you have of it?

3 A The fact that I had to put it  
4 together.

5 Q Okay.

6 A The circumstances surrounding it.

7 Q Was there more than one product  
8 being recalled at that time?

9 A Yes.

10 Q Were you involved in the press  
11 release for the other products?

12 A I don't recall there being a  
13 press -- no, I don't recall being involved in  
14 any of the other press releases at the time.

15 Q Did you have someone put together a  
16 draft for you, or did you actually write the  
17 press release?

18 A I think I may have put it together  
19 myself using a template. I'm not -- I'm not  
20 entirely sure of the specifics.

21 MR. MILLER: I'm going to hand  
22 you what I'm going to mark as  
23 Exhibit 219.

24 (Plaintiff's Exhibit No. 219

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1 was marked for identification.)

2 BY MR. MILLER:

3 Q Let me know when you've had a chance  
4 to read this, ma'am.

5 A Okay.

6 Q Ma'am, you agree with me this is an  
7 e-mail generated by you on Thursday,  
8 April 24th, 2008?

9 A Correct.

10 Q Okay. And the subject matter is  
11 News Release?

12 A Correct.

13 Q And you agree that's the same thing  
14 as the press release that we were just  
15 discussing?

16 A Agreed.

17 Q And it's got an attachment which  
18 we'll discuss in a second. But looking at the  
19 context of what is in this e-mail, it's from  
20 you to Chris Benson?

21 A Correct.

22 Q And who is Chris Benson?

23 A Honestly I don't even recall.

24 Q Okay. Well, let's take a look at

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1        what you wrote. It says: "Please note that  
2        this press release is still in draft as the  
3        FDA has just communicated that we need to  
4        recall all lots of Digoxin Tablets (all  
5        strengths)."

6                        MR. ANDERTON: Pete, do you  
7        have another copy? For some reason, the  
8        "to" is obliterated in my copy, not in  
9        hers, not in yours.

10                      MS. CARTER: I can switch with  
11        you.

12                      MR. MILLER: If you've got one,  
13        that would be great.

14                      MR. ANDERTON: Wait. Same  
15        thing.

16                      MR. MILLER: I'll have to get  
17        that copy to you because I have lots of  
18        copies and not this one.

19                      MS. CARTER: What's the Bates  
20        number on this?

21                      MR. MILLER: The Bates number  
22        of mine is Actavis 0140080.

23                      MR. ANDERTON: Not mine.

24                      MR. MILLER: Do you want to

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1 reviews hers before I go on?

2 MR. ANDERTON: I would

3 actually.

4 MR. MILLER: Okay. Go ahead.

5 MR. ANDERTON: Thanks.

6 Okay. If you can get me --

7 MR. MILLER: I certainly will.

8 MR. ANDERTON: I'm sorry. Give

9 me the Bates range on that one more time.

10 MR. MILLER: I will. 00140080.

11 MR. ANDERTON: 140080. Got it.

12 Thanks.

13 BY MR. MILLER:

14 Q Ma'am, going back to what the  
15 contents of this document are, I read that  
16 first sentence. For clarity, I'm just going  
17 to go ahead and do it again.

18 What you typed is: "Please note  
19 this press release is still in draft as the  
20 FDA has just communicated that we need to  
21 recall all lots of Digoxin Tablets (all  
22 strengths)."

23 My question to you is: Does that  
24 statement refresh your recollection of whether

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1 or not this recall was voluntarily done on the  
2 part of the company or voluntarily done at the  
3 request of the FDA?

4 MR. ANDERTON: Objection.

5 You may answer.

6 THE WITNESS: Again, it was  
7 communicated to the FDA, but the decision  
8 to recall had already been made by the --  
9 Robert Wessman.

10 BY MR. MILLER:

11 Q Were you aware that the decision to  
12 recall by Robert Wessman had already been made  
13 of all lots prior to April 24th of 2008?

14 A No. I found out when the FDA recall  
15 coordinator called me.

16 Q Is there anything in writing that  
17 you saw that would suggest that Robert Wessman  
18 made this decision prior to the request of the  
19 FDA, request by the FDA?

20 A No.

21 Q Would you agree that up to this time  
22 of this e-mail, you were concentrating on a  
23 recall of just one lot?

24 A Correct.

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1 Q And your press release was  
2 concentrated on just one lot up to this point  
3 in time; is that correct?

4 A Correct.

5 Q And where did you go -- what did you  
6 do to get your research in order to alter the  
7 draft press release from a one-lot press  
8 release to a multiple- or all-lot press  
9 release?

10 A Where did I get the information  
11 from?

12 Q Yes.

13 A From various people.

14 Q Which people did you talk to?

15 A I don't recall specifically, but I  
16 would need a lot of people to provide me with  
17 the information.

18 Q Fair enough. Let's take a look at  
19 the attachment. And it's stated "News  
20 release."

21 Who's the intended target when you  
22 draft this, if you know?

23 A I'm assuming it's everyone.

24 Q Would you agree that it's targeted

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1 to individual consumers that have been  
2 prescribed the pharmaceutical that's being  
3 recalled, specifically Digitek?

4 A It can be any -- I mean, it could be  
5 the consumer or could be someone who knows a  
6 consumer.

7 Q My question is: You're not writing  
8 this for -- specifically for doctors? You  
9 wouldn't want to write it at such a level that  
10 a doctor would understand it but the -- but  
11 someone who's actually ingested the pill would  
12 be able to understand it; is that correct?

13 A Correct.

14 Q And is it your job title -- when did  
15 you find out that it was your job title to  
16 write the press release?

17 MR. ANDERTON: Objection.

18 You may answer.

19 THE WITNESS: It has never been  
20 my -- it wasn't a job title.

21 BY MR. MILLER:

22 Q Right.

23 A It was requested of me to draft one.

24 Q And this is the attachment, if we

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1 turn the page: News release. And it was  
2 Actavis Totowa recalls one lot of Digitek  
3 digoxin tablets, USP 125 -- what's mcg?

4 A Microgram.

5 Q -- micrograms as precaution.

6 Did that language come from you, or  
7 were you given the title of this document?

8 A I don't recall.

9 Q If we go down to -- and I'm going to  
10 take a look at the fourth paragraph down. And  
11 it says: "Digoxin is used to treat heart  
12 failure and abnormal heart rhythms."

13 You don't have any medical training;  
14 right?

15 A No.

16 Q Where would you have gotten this  
17 medical information from?

18 A I don't recall specifically where I  
19 got this one, but I may have gotten it from  
20 medical affairs or I might have gotten it from  
21 the insert, the product insert.

22 Q Okay. Fair enough.

23 And it goes on to say: "The  
24 existence of double strength tablets poses a

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1 risk of digitalis toxicity in patients with  
2 renal failure."

3 Did I read that correctly?

4 A Correct.

5 Q And when you wrote this, did you see  
6 this as a way to warn those that have been  
7 prescribed digoxin and are taking digoxin of  
8 the potential risk of the issues that were  
9 found with the lot that you originally were  
10 writing the press release for?

11 MR. ANDERTON: Objection.

12 You may answer.

13 THE WITNESS: Can you ask the  
14 question again?

15 MR. MILLER: Would you read  
16 that one back.

17 (The court reporter read the  
18 preceding question.)

19 THE WITNESS: I didn't -- my  
20 intent was basically to indicate what the  
21 dangers may be. Whether it was to warn  
22 them or whatnot, that -- I just wrote  
23 what the issues may -- what may occur for  
24 consumers.

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1 BY MR. MILLER:

2 Q Did you have a sense it was  
3 important to be clear and concise in the  
4 information that you were putting in the  
5 letter?

6 A To an extent, yes.

7 Q Okay. Did anyone in regulatory  
8 affairs or anyone at the company above you  
9 review this and approve it?

10 A Yes.

11 Q And who would that be?

12 MR. ANDERTON: I'm going to  
13 object.

14 You can identify the people  
15 that approved it, but do not reveal any  
16 privileged communication. Any  
17 communication with counsel relating to  
18 the review and approval, you don't reveal  
19 that.

20 THE WITNESS: Okay.

21 I believe Phyllis Lambridis  
22 reviewed it. I believe John LaRocca  
23 reviewed it. I believe the Actavis  
24 press -- the external communications

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1 individual, Hjordis, reviewed it.

2 BY MR. MILLER:

3 Q And John LaRocca, he's senior legal  
4 for Actavis?

5 MR. ANDERTON: "LaRocca."

6 BY MR. MILLER:

7 Q LaRocca. Is that correct?

8 A I believe so.

9 Q And without offering up any  
10 conversations you had with him, did he change  
11 the document in any way as you recall?

12 MR. ANDERTON: Objection. And  
13 I instruct the witness not to answer.

14 MR. MILLER: I'm looking for a  
15 yes or no. I'm not looking for any  
16 content.

17 MR. ANDERTON: You're getting  
18 into information that reveals -- I mean,  
19 if he did, that's going to reveal legal  
20 advice, legal strategy. I instruct the  
21 witness not to answer.

22 BY MR. MILLER:

23 Q It is -- has a signature or  
24 identifies a point of contact for inquiries at

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1 the bottom. It's Sarita Thapar. Did you work  
2 with her on drafting this?

3 A "Sarita Thapar."

4 Q Thapar? Thank you. Did you work  
5 with Sarita Thapar on this document?

6 A I don't recall.

7 MR. MILLER: I want to hand you  
8 what I'm going to mark as Exhibit 220.

9 (Plaintiff's Exhibit No. 220  
10 was marked for identification.)

11 THE WITNESS: I believe you  
12 gave me two copies.

13 MR. MILLER: Oh, thank you very  
14 much.

15 BY MR. MILLER:

16 Q Let me know when you've had a chance  
17 to review this, please.

18 All set, ma'am?

19 A Yes.

20 Q And this is -- well, have you ever  
21 seen this document before?

22 A Yes.

23 Q You have? And under what occasion  
24 would you have seen this?

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1           A     Probably while I was performing  
2     activities for the recall.

3           Q     Okay. And this is April 25th, 2008,  
4     the day after the e-mail we just discussed  
5     with the draft press release. Would you have  
6     received this from Sarita Thapar?

7           A     Most probably.

8           Q     And it is from OMEGA Corporate and  
9     Occupational Health Services. Do you recall  
10    working with them?

11          A     I may have, yes.

12          Q     And it says: Dear Sarita -- it's  
13    from the OMEGA Corporate and Occupational  
14    Health Services -- please find enclosed the  
15    HHEs that you have Dr. Leikin review.

16                What's an HHE?

17          A     A health hazard evaluation.

18          Q     Okay. And it says: As we  
19    discussed, the -- redacted -- is still being  
20    typed up and yet to be sent for signature by  
21    your office.

22                If we turn the page, is -- you had a  
23    chance to read this. Is this the HHE where  
24    you received the information to put in the

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1 press release?

2 A I may have. I don't recall.

3 Q Did you ever have occasion to  
4 discuss anything with Dr. Leikin?

5 A In regards to?

6 Q Regards to Digitek health concerns.

7 A I don't recall.

8 Q If you would have, would you have  
9 kept a record of it in any way?

10 A If it was an e-mail, it might have  
11 been an e-mail. Otherwise, if it was a  
12 telephone conversation, I don't recall.

13 Q If we take a look at the language  
14 Clinical conclusion, and it states:  
15 "Potential risks to the patient depend upon  
16 the constituency of the tablets. If the  
17 tablets contain double the dose, then it can  
18 be expected that digitalis toxicity can occur  
19 in individuals taking daily doses or in  
20 patients with renal insufficiency."

21 Did I read that correctly?

22 A Yes.

23 Q And I can put the other exhibit on  
24 there, but you also discussed patients with

1       renal insufficiency in the press release.  
2       Would you agree that this is where the  
3       language was taken from or would you like to  
4       take the time to compare the two?

5             A       I don't recall.

6             Q       Let's go back to -- and you should  
7       have it in front of you -- what was marked  
8       Exhibit 219, just an exhibit back there. And  
9       take a look at the press release, the draft  
10      of.

11                   And here we discussed it says:  
12      "Digoxin is used to treat heart failure and  
13      abnormal heart rhythms. The existence of  
14      double strength tablets poses a risk of  
15      digitalis toxicity in patients with renal  
16      failure."

17                   Did you have a feeling that that  
18      statement was true?

19                   MR. ANDERTON: Objection.

20                   She's already testified she has no  
21      medical training.

22      BY MR. MILLER:

23             Q       You can answer.

24             A       I have no medical training.

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1           Q     Well, I'm not going to argue that  
2 point. But you wanted to be honest when you  
3 relayed information to users of the product  
4 via a press release; is that correct?

5           A     Correct.

6           Q     Okay. And it's important to warn  
7 them about potential health risks; is that  
8 correct?

9                     MR. ANDERTON: Objection.

10                    You may answer.

11 BY MR. MILLER:

12           Q     Is that correct?

13           A     You would want to -- I mean, again,  
14 it's not ultimately my decision as to what the  
15 press release contains. But, you know, the  
16 information should be there to alert the  
17 consumers of the product what the -- what  
18 could occur.

19           Q     And you agree that you used the HHE,  
20 the health hazard evaluation, from Dr. Leikin  
21 as part of the input for your draft?

22                     MR. ANDERTON: Again,  
23 objection. That mischaracterizes her  
24 testimony. You asked her that and she

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1           says she didn't know.

2       BY MR. MILLER:

3           Q     It's okay to answer.

4                       THE WITNESS: I -- again, as I  
5           indicated before, I don't recall where I  
6           got the information from, whether it was  
7           from medical affairs, you know, through  
8           this health hazard evaluation, whether it  
9           was from a product insert. I don't  
10          recall.

11       BY MR. MILLER:

12           Q     Fair enough. Let's go back to  
13          Exhibit 219 -- I lied.

14                       MR. MILLER: What's this last  
15          one, Meghan?

16                       MR. ANDERTON: 220.

17       BY MR. MILLER:

18           Q     Let's go back to Exhibit 220, the  
19          HHE received from the doctor.

20                       MR. ANDERTON: After the press  
21          release was issued?

22                       MR. MILLER: After the press  
23          release -- well, I don't believe it's  
24          been issued. We have a draft.

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1 MR. ANDERTON: Why don't you  
2 look at the cover letter for the press  
3 release or for the HHE.

4 MR. MILLER: I appreciate your  
5 input, but I'm going to move on.

6 BY MR. MILLER:

7 Q Let's look at the HHE --

8 MR. ANDERTON: We want it to be  
9 accurate.

10 MR. MILLER: Is accuracy  
11 important? We're going to get into that,  
12 Mike. If it's important to be  
13 accurate -- well, never mind. We're  
14 going to move on. I see the date.

15 BY MR. MILLER:

16 Q This HHE from Dr. Leikin, he states  
17 in his clinical conclusion -- and I'm going to  
18 read it again, the sentence that starts with  
19 "If the tablets contain."

20 Do you see that?

21 A Yes.

22 Q He says: "If the tablets contain  
23 double the dose, then it can be expected that  
24 digitalis toxicity can occur in individuals

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1 taking daily doses or in patients with renal  
2 insufficiency."

3 Do you see that?

4 A Yes.

5 Q Do you understand that's two  
6 different groups of people? That's people who  
7 are taking a daily dose or people that have  
8 renal insufficiency? Did you understand that  
9 when you read the HHE?

10 A Okay. Yes.

11 Q You did? Okay. Thank you.

12 Did you have any communications with  
13 Dr. Leikin regarding that specific topic if  
14 this pertained to both groups of individuals,  
15 those that take a daily dose or those that  
16 have renal insufficiencies?

17 MR. ANDERTON: Objection; asked  
18 and answered.

19 You may answer.

20 THE WITNESS: I don't recall.

21 MR. MILLER: I'm going to hand  
22 you what I'm going to mark as  
23 Exhibit 221.

24 (Plaintiff's Exhibit No. 221

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1 was marked for identification.)

2 BY MR. MILLER:

3 Q Take a moment to review it or  
4 however much time you need.

5 MR. ANDERTON: In light of the  
6 size of this document, do you want to go  
7 off the record for a few minutes so she's  
8 not reviewing it on camera?

9 MR. MILLER: That's fine.  
10 Let's go off the record.

11 THE VIDEOGRAPHER: Off the  
12 record at 12:19 p.m.

13 (Discussion off the record.)

14 THE VIDEOGRAPHER: Back on the  
15 record at 12:24 p.m.

16 BY MR. MILLER:

17 Q Ma'am, what I've handed you is  
18 Actavis Document 0028178, been marked  
19 Plaintiff's Exhibit 221. And have you seen  
20 this document before?

21 A Yes.

22 Q What is this document, ma'am?

23 A It's a recall package for digoxin.

24 Q And is it a recall package that you

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1 reviewed and approved?

2 A Yes.

3 Q And is that your signature --

4 A Yes.

5 Q -- on the bottom line?

6 Okay. And, ma'am, you'd agree with  
7 me you reviewed and approved it by May 23rd of  
8 2008?

9 A I reviewed and approved it on  
10 May 23rd.

11 Q Okay. And do you have a memory of  
12 going through this document and when you  
13 reviewed it and approved it, as you sit here  
14 now?

15 A Yes.

16 Q And it was prepared by a Connie T.  
17 Truemper?

18 A "Truemper."

19 Q Truemper. And who was Connie?

20 A She's a senior compliance officer.

21 Q Did you work with -- did she report  
22 to you directly?

23 A No.

24 Q Who did she report to?

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1           A     At the time I believe she also  
2           reported to Tony Delicato.

3           Q     Okay. And it says prepared by her.  
4           Did you work with her in preparing this  
5           document?

6           A     Yes, to an extent.

7           Q     Okay. And the document -- is this  
8           document prepared for the FDA?

9           A     Yes.

10          Q     And is it part of the requirements  
11          when a product is recalled as per the Codified  
12          Federal Rules?

13          A     Yes.

14          Q     And did you have those rules with  
15          you? I believe it's Section 710 of the  
16          Federal Rules. Would you have reviewed those?

17          A     I may have.

18          Q     And if we look at the second page,  
19          it's the Recall Package 2008; Product:  
20          Digitek; Page 2 of 21; and Type of Recall:  
21          Class 1.

22                   Is this a form that was empty, like  
23          a boilerplate? I don't know what the other  
24          term would be. But was there a blank form

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1       that you filled out, or was this form  
2       generated from scratch, if you understand what  
3       I'm saying?

4             A       This form is a template.

5             Q       Okay. But this is the final  
6       document; correct?

7             A       Yes.

8             Q       Okay.

9             A       But you're asking the form in  
10       general.

11            Q       Well, I was just curious if there  
12       was -- how was it generated? Was it started  
13       where they -- is there a template to follow,  
14       or was it generated from scratch?

15            A       No. There was a template to follow.

16            Q       And if we go to Page Actavis 028180,  
17       and it says reason for recall, and it's the  
18       first block: How product is defective and/or  
19       violative; is that correct?

20            A       Correct.

21            Q       And where did you get the  
22       information that states -- or did you gather  
23       the information that says: "Digoxin tablets  
24       exceeded tablet thickness specifications"?

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1 A This was prepared not by me.

2 Q Okay.

3 A So you would have to ask the person  
4 who prepared it.

5 Q Okay. I don't have handy the person  
6 who prepared it. But as the person who  
7 reviewed it, did you do any information beyond  
8 just reading that information to determine if  
9 you were going to approve this document or  
10 not? Did you do any research?

11 A In what regards?

12 Q My question is: Did you just read  
13 it and assume it was correct and move on, or  
14 did you do any document review or any type of  
15 review in order to determine if it was  
16 accurate?

17 A This particular statement?

18 Q Yes.

19 A I don't recall.

20 Q And it goes on to say how the  
21 problem was discovered. And it states:  
22 "During the packaging operation of Lot  
23 70924A1, the packaging operator observed  
24 tablets with approximately double the

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1 thickness on the counter channel."

2 And date discovered 11/30/2007.

3 You recognize that as an incident  
4 that we've discussed here today?

5 A I recognize the lot number, yeah.  
6 It might have been the same incident we  
7 discussed earlier.

8 Q At the time you reviewed this, this  
9 document, did being informed that that was the  
10 date it was discovered, did that trigger any  
11 review to see if historically this was an  
12 issue beyond that one lot?

13 A I'm sorry? Restate the question,  
14 please.

15 Q When you reviewed this document and  
16 put your signature on it that you reviewed and  
17 approved it, did reading the date of discovery  
18 and how the problem was discovered, did that  
19 trigger for you a reason to go back and  
20 historically look at data for this product?

21 A I don't recall.

22 Q If we go to Page 6 of 21 in the  
23 upper right corner of this document, it says:  
24 Recall Strategy continued.

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1 Do you see that, ma'am?

2 A Yes.

3 Q Rationale for Consumer level. It  
4 says: "Due to the severity of the health  
5 risk, we recommend a Level I recall."

6 Do you know who entered those words  
7 into this report?

8 A I'm assuming the person who prepared  
9 it.

10 Q Okay. You believe that information  
11 came from Connie Truemper?

12 A Yes.

13 Q I want to go to -- if you look at  
14 the bottom right corner, it's got the Bates  
15 number. And I want to go to 28204. The last  
16 three digits are 204.

17 Do you see that?

18 A Yes.

19 MR. ANDERTON: One more time,  
20 please, Pete.

21 MR. MILLER: Yes. Lower right  
22 corner, 204.

23 MR. ANDERTON: Thank you.

24

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1 BY MR. MILLER:

2 Q And, ma'am, do you see where it says  
3 this is Attachment V, Health Hazard  
4 Evaluation?

5 A Yes.

6 Q And if we turn the page, if you'll  
7 take a look at that, do you agree that this is  
8 the same health hazard evaluation that we  
9 reviewed previously with the same date,  
10 18 April 2008, by Dr. Leikin?

11 A It appears to be.

12 Q Okay. And you agree that when you  
13 approved this document with Attachment V, that  
14 Dr. Leikin's health hazard evaluation included  
15 the line in the fourth paragraph here starting  
16 with "If": "If the tablets contain double the  
17 dose, then it can be expected that digitalis  
18 toxicity can occur in individuals taking daily  
19 doses or in patients with renal  
20 insufficiency"?

21 Did I read that correctly, ma'am?

22 A Yes.

23 Q Now, if we go to -- look at 213 in  
24 the lower right corner.

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1 MR. ANDERTON: Do you mean

2 Bates Range 213?

3 MR. MILLER: I do.

4 MR. ANDERTON: Thank you.

5 BY MR. MILLER:

6 Q Actually, I'd like to back up and  
7 look at 208, if you would, please. And this  
8 is Urgent: Drug Recall, Attachment 6. And  
9 it's a letter April 28, 2008, and it's "Dear  
10 Valued Customer."

11 When you reviewed this document for  
12 the FDA and signed that you approved it, did  
13 you have an understanding of who the customer  
14 was for the product?

15 A Yes.

16 Q And do you have an understanding  
17 that -- who is the customer?

18 A Anyone who consumes or knows of  
19 anyone who consumes this drug.

20 Q Do you know if this letter was sent  
21 to individuals who were prescribed the drug?

22 A Being that it was a Class I recall,  
23 it should have been sent to all customers -- I  
24 mean all individuals who take this product.

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1           Q     Would you be surprised if I told you  
2     there's been testimony that customers used in  
3     this form is not the individual who's  
4     prescribed the drug but the customer who  
5     purchased the product from Actavis?

6                     MR. ANDERTON:  Objection.

7                     THE WITNESS:  I'm sorry?

8                     MR. ANDERTON:  Mischaracterizes  
9     prior testimony.

10                    You may answer.

11                    THE WITNESS:  Can you state --  
12     can you ask the question again?

13                    MR. MILLER:  Well, we'll strike  
14     that.

15     BY MR. MILLER:

16           Q     And you agree that in this letter --  
17     or actually strike that.

18                    In this Urgent:  Drug Recall,  
19     April 28, 2008, letter, "Dear Valued  
20     Customer," if you'd come down with me in the  
21     paragraph, it states that -- starting with the  
22     word "Depending on the constituency" --

23                    MR. ANDERTON:  "Constituency"?

24                    MR. MILLER:  I don't know.  Am

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1 I saying that right? That's a brand-new  
2 one on me.

3 MR. ANDERTON: "Constituency."

4 BY MR. MILLER:

5 Q I don't understand why that's so  
6 difficult, but do you see the line I'm  
7 reading?

8 A Yes.

9 Q "Depending on the constituency of  
10 the tablets, double the dose is taken, it can  
11 be expected that digitalis toxicity can occur  
12 in individuals taking daily doses or in  
13 patients with renal insufficiency."

14 I think I finally read that right.  
15 Do you agree I read that right, ma'am?

16 A Yes.

17 Q And do you agree that it's important  
18 for consumers, those that are prescribed this  
19 product, to know that it can cause toxicity in  
20 both those that take daily doses and those  
21 that have renal insufficiency as it's worded  
22 here?

23 A Okay. Yes.

24 Q You do? Okay. Well, let's go to

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1       213. And this is Attachment 8 of the  
2       document, and it's titled "News release."

3               Now, do you recall reviewing this  
4       document when you approved this entire recall  
5       package for the FDA?

6               A     Yes.

7               Q     Okay. And the press release or news  
8       release that is going to go out states,  
9       starting here with "Digitek" in the third  
10      paragraph: "Digitek is used to treat heart  
11      failure and abnormal heart rhythms. The  
12      existence of double strength tablets poses a  
13      risk of digitalis toxicity in patients with  
14      renal failure."

15              Ma'am, do you see anywhere in this  
16      news release that it shows a potential risk of  
17      digitalis toxicity to those who take a daily  
18      dosage?

19                      MR. ANDERTON: Objection;  
20              mischaracterizes the document.

21              BY MR. MILLER:

22              Q     Do you see it anywhere in there,  
23      ma'am?

24                      MR. ANDERTON: You may answer.

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1 THE WITNESS: I'm sorry. Can  
2 you ask the question again?

3 MR. MILLER: Would you repeat  
4 that back, please.

5 (The court reporter read the  
6 record as follows:

7 "QUESTION: Okay. And the  
8 press release or news release that is  
9 going to go out states, starting here  
10 with "Digitek" in the third paragraph:  
11 "Digitek is used to treat heart failure  
12 and abnormal heart rhythms. The  
13 existence of double strength tablets  
14 poses a risk of digitalis toxicity in  
15 patients with renal failure."

16 Ma'am, do you see anywhere in  
17 this news release that it shows a  
18 potential risk of digitalis toxicity to  
19 those who take a daily dosage?")

20 THE WITNESS: It doesn't  
21 indicate -- I mean, it goes on further to  
22 indicate that digitalis toxicity can  
23 cause nausea, vomiting, dizziness, low  
24 blood pressure, cardiac instability, and

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1           bradycardia.

2       BY MR. MILLER:

3           Q     It does. I see that, ma'am. But  
4     the way I would read that is it does all those  
5     things to someone who receives digitalis  
6     toxicity because they have renal failure.

7                     Do you see anywhere in this document  
8     that digitalis toxicity can cause nausea,  
9     vomiting, dizziness, low blood pressure,  
10    cardiac instability, and bradycardia in  
11    someone who takes a daily dose?

12                    MR. ANDERTON: Objection. The  
13    document speaks for itself.

14    BY MR. MILLER:

15           Q     You can answer.

16           A     I -- it depends on -- I don't -- it  
17    depends on who reads it. I can't answer for  
18    someone who's reading it and what they're  
19    taking from this document.

20           Q     Someone who's reading it is relying  
21    on you, the drafter of the press release and  
22    someone who's approving the recall package, in  
23    order to make sure that the right words are  
24    used; would you agree with that?

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1           A     Not necessarily. They're relying  
2     on, you know, a whole -- a bunch of people.  
3     And keep in mind that this news release is  
4     approved by the FDA before it gets sent out.

5           Q     You send this to the FDA; is that  
6     correct?

7           A     Correct.

8           Q     And so the FDA is relying on you to  
9     review this recall before it's sent. You've  
10    signed it reviewed and approved; correct?

11          A     I -- no. The press release was sent  
12    before the package was reviewed and approved.  
13    And the news release was approved by the FDA  
14    prior to me reviewing and approving this  
15    recall package.

16          Q     Do you feel this news release  
17    adequately warns those that are prescribed  
18    Digitek of the potential health risks?

19          A     It indicates what the issues are.  
20    As far as how accurately, I mean, it indicates  
21    what the issues with it are and what the  
22    dangers of it are.

23                   MR. MILLER: Lunch?

24                   THE VIDEOGRAPHER: This

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1 completes Videotape No. 2. Off the  
2 record at 12:41 p.m.

3 (Luncheon recess taken from  
4 12:41 p.m. to 1:28 p.m.)

5 THE VIDEOGRAPHER: This is  
6 Videotape No. 3. Back on the record at  
7 1:28 p.m.

8 BY MR. MILLER:

9 Q Ma'am, I'd like to switch gears, now  
10 that we've had lunch, and talk about product  
11 complaints. And I'm correct in stating that  
12 you were involved in the Digitek product  
13 complaints following the recall?

14 A Yes.

15 Q Tough word to get out.

16 I'd like to hand you what I have  
17 marked as Exhibit 222.

18 (Plaintiff's Exhibit No. 222  
19 was marked for identification.)

20 BY MR. MILLER:

21 Q After you've had a chance to review  
22 it, I have a couple questions.

23 All set? This document is titled  
24 "Actavis Product Complaint Form." Not that

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1       you would remember this specific one, do you  
2       remember the form in general?

3             A       Yes.

4             Q       Is it the same product complaint  
5       form that would have been used for a product  
6       complaint prior to the Digitek recall?

7             A       Yes.

8             Q       And is there a separate form that  
9       would be used for adverse events that we  
10      addressed earlier?

11            A       I don't believe so. Not in this  
12      case, no.

13            Q       Okay. And if we look at this, it's  
14      dated 9/15/2008. You agree that's after the  
15      recall; correct?

16            A       Correct.

17            Q       And it's difficult to read there,  
18      Product Name, but it's digoxin tablets,  
19      .125 milligrams. My question is: If we go to  
20      the Nature of the Complaint and it states:  
21      "Was using Digitek and ended up in a  
22      hospital," from our previous discussion, I was  
23      under the influence that an adverse event was  
24      more of a health issue and a product complaint

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1 issue about the product would have been  
2 something that would have wound up on a form  
3 like this?

4 A It is a medical issue.

5 Q Right.

6 A It's an adverse event. However,  
7 even if you have an adverse event to assess  
8 that nothing -- there was nothing that may  
9 have caused that adverse event, you are still  
10 dictated to review any sort of batch records  
11 or any records that pertain to the processing  
12 of the product to assure that everything was  
13 manufactured in accordance with the internal  
14 specifications and regulatory requirements.  
15 So you do a review to ensure that that was  
16 done.

17 Q And if it was determined that the  
18 use of Digitek resulted in this complaint or  
19 the individual who called in regarding this  
20 complaint did go to the hospital, would this  
21 be elevated to an adverse event?

22 A It was already an adverse event  
23 because if you look at the form, it says  
24 "Type" and it's indicated as Medical.

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1 Q Okay. Help me with that. Where are  
2 you on the form?

3 A If you -- do you see where it says:  
4 Digoxin tablets .125-milligram?

5 Q I do.

6 A And on the right side it says Lot  
7 number, Expiration date, and then it says  
8 Type.

9 Q Yes.

10 A The Medical box is checked off.

11 Q Okay. So the fact that the Medical  
12 box is checked off is --

13 A Means --

14 Q It's an adverse event?

15 A Correct.

16 Q Do you recall receiving a high  
17 volume of these following the Digitek recall?

18 A Yes, definitely.

19 Q Did that become the majority of your  
20 time spent at work was dealing with these  
21 following the recall?

22 A It was one of the things that I was  
23 reviewing.

24 Q Did you assemble a team or any

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1 additional personnel to help you with the  
2 processing of these product complaints?

3 A I -- yes. I had one other  
4 individual who helped me.

5 Q And who was that?

6 A Daniel Comrie.

7 Q And what was her title?

8 A She was the complaint specialist in  
9 Elizabeth.

10 Q And Sarita Thapar worked with  
11 adverse events; is that correct?

12 A Correct.

13 Q And if marking the Medical box in  
14 the field that we just discussed would dictate  
15 that this is an adverse event, would Sarita  
16 Thapar have been involved in these forms as  
17 well?

18 A Yes. If you look on the last page  
19 of this packet --

20 Q Yes.

21 A -- this is the initial notification  
22 that quality assurance received. And if you  
23 look at the top, it indicates Actavis Medical  
24 Affairs Case Form.

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1 Q Yes.

2 A So that's the initial notification  
3 that we get. And if you -- where it says:  
4 2.0, Triage Medical Affairs, if you go about  
5 two thirds down --

6 Q Okay. Yes, I'm there.

7 A You see where it says "AE"?

8 Q Yes.

9 A That indicates adverse event. That  
10 is generated by the medical affairs group,  
11 which is headed by Sarita Thapar.

12 Q All right. And if we go along there  
13 where it says "Triage Medical Affairs" and the  
14 AE we've established is adverse event, Case  
15 Priority, who is it that identifies that this  
16 is going to be expedited, nonexpedited, or PC  
17 or MI only?

18 A That would be medical affairs.

19 Q Okay. And do you know what "PC or  
20 MI only," do you know what the "PC" stands  
21 for?

22 A "PC" stands for product complaint.

23 Q And what does "MI" stand for?

24 A Medical inquiry.

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1 Q And it says "Triaged by." Do you  
2 know what the "CF" signifies?

3 A The individual who took in the  
4 complaint or acknowledged the complaint.

5 Q And triage date, then, would be the  
6 initial call?

7 A Or the initial -- when this  
8 individual triaged it.

9 Q And in this case it would have been  
10 August 1st of 2008; do you agree?

11 A Correct.

12 Q Then if we go back to the first  
13 page, what process would this document have  
14 gone through, if you know, between August 1st  
15 of 2008 and roughly 45 days later to  
16 September 15th of 2008? What was the process?

17 A Again, there was an overwhelming  
18 number of complaints that were received by  
19 Actavis as a result of this Class I recall.  
20 And in doing so, basically they would upload  
21 them into the system.

22 The problem was there were so many  
23 that they weren't being -- we, the quality  
24 group, couldn't process them quickly enough.

1 So, therefore, when the quality assurance  
2 group actually received it, when they -- not  
3 acknowledge it, but when they actually got  
4 around to this particular complaint that was  
5 issued, you know, that was triaged on 8/1, it  
6 was actually 9/15. So there's an explanation  
7 of it in this packet as well.

8 Q And if we look for that explanation,  
9 would you agree with me that -- actually,  
10 let's turn to Page 804 in the lower right  
11 corner. And it starts out with Complaint  
12 File: C08-3790. Would you break down the  
13 complaint file? What's the significance of  
14 C08-3790?

15 A That's the number used to annotate  
16 the complaint.

17 Q Would it be accurate to say that  
18 this is the 3,790th complaint in 2008?

19 A Correct.

20 Q And were the vast majority of those  
21 3,790 complaints related to Digitek?

22 A Yes.

23 Q And the next statement says: "The  
24 lot number is unknown, therefore no formal

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1 investigation to include records review or  
2 retention sample evaluation is possible."

3 As the senior manager of quality  
4 assurance investigation group, what steps did  
5 you take in order to determine what the lot  
6 number was that corresponded with a particular  
7 complaint?

8 A Well, given that this was an adverse  
9 event, this is something that the medical  
10 affairs group would have to take all  
11 applicable steps to obtain the lot number --

12 Q Okay. So --

13 A -- from the complainant.

14 Q Fair enough. So you're saying it  
15 was Sarita Thapar's responsibility or her  
16 department to determine what the lot number  
17 was?

18 A If one could be obtained.

19 Q Who would have generated this page  
20 that we're looking at here? Would it have  
21 been your department or Sarita Thapar's?

22 A No. It would be my -- my  
23 department.

24 Q It goes on to say at the bottom: As

1 a result of QA Investigation 07-093, where two  
2 digoxin tablets .125-milligram were found with  
3 approximately double the thickness, all  
4 batches of digoxin have been voluntarily  
5 recalled as a precautionary measure.

6 Where did you get that information,  
7 specifically the fact that two digoxin tablets  
8 with approximately double the thickness were  
9 found?

10 A Well, it would have to be in this  
11 investigation that was referenced.

12 Q As you sit here today, do you know  
13 the total number of, approximately,  
14 double-thick tablets were found in that lot?

15 A I have -- I don't recall.

16 Q Where would this form go other than  
17 being stored at the company, the completed  
18 product complaint form, this one and all  
19 others? Do they wind up being delivered to  
20 the FDA or just stored in the company? What's  
21 the ultimate destination of this document?

22 A Well, basically given that this was  
23 a medical affairs complaint, we would provide  
24 them all the information that we had. So they

1 would close out their adverse event complaint.  
2 We would hold onto the originals of the  
3 information that we have and store it for  
4 any -- yeah, if FDA requested to see it or  
5 just within our retention policies.

6 Q Does a copy of it go to the  
7 complainant, the person who actually filed the  
8 original complaint?

9 A With the medical affairs, I'm not  
10 really quite sure. That would be -- medical  
11 affairs handles it, so I don't know. They  
12 would be responsible.

13 If it was an adverse event, it would  
14 be the medical affairs group that would be  
15 responsible for communicating anything to the  
16 complainant or -- to the complainant.

17 Q If it was a product complaint and  
18 not an adverse event, would a copy of the  
19 document be sent to the person who called in  
20 the original complaint?

21 A If it was a product complaint, we  
22 would send a letter indicating what actions we  
23 took and what the results of that  
24 investigation or batch record review or

1 anything entailed. We would send a letter to  
2 the complainant.

3 Q Would that letter include a copy of  
4 the press release?

5 A The press release has to do with --  
6 again, it depends what the product complaint  
7 is for.

8 Q Fair enough. If we turn to the next  
9 page, Page 805, there's a copy of the press  
10 release maintained within this product  
11 complaint. Was it typical that a copy of the  
12 press release was included in a product  
13 complaint?

14 A Excuse me?

15 Q Was it typical -- I'm just trying to  
16 determine why this product complaint has a  
17 copy of the press release attached.

18 A Again, it's not a product complaint.  
19 It's an adverse event. But the reason that  
20 they included the press release is basically  
21 to provide evidence that all batches had been  
22 voluntarily recalled and to basically justify  
23 the statement that was made on the previous  
24 page.

1           Q     If we look on the next page, 806,  
2           and this is a letter, if I'm correct, to the  
3           complaint file?

4           A     Correct.

5           Q     And it's from Shonise Moses?

6           A     Correct.

7           Q     And who is she?

8           A     She was a complaint coordinator.

9           Q     And it's regarding justification for  
10          the subject complaint not being processed upon  
11          receipt from medical affairs. And it states  
12          that the complaint, to paraphrase, was not  
13          processed due to the overwhelming number of  
14          complaints received during the first week of  
15          May 2008 due to the Class I Digitek recall.

16                If this is an adverse event and not  
17          a product complaint, why would it be that you  
18          would have reviewed and signed this document?

19          A     Because given that we -- it's a --  
20          even though it's a medical -- an adverse  
21          event, there's a quality system in place. And  
22          I indicated to you that you have to annotate,  
23          process, and document compliantly the receipt  
24          of any complaints, whether they are adverse or

1       whether they are technical.

2               So you want to make -- again, the  
3       whole reason for this is that you see this  
4       elapsed time frame; you want to justify if  
5       anyone from a regulatory body were to review  
6       this complaint, what the reason for this delay  
7       was.

8               Q       Were the complaints scanned in to  
9       any typical -- or was there a software that  
10      controlled all the complaints?

11              A       What do you mean by "software"?

12              Q       Well, once these documents were  
13      gathered together and if it fell under the  
14      category of product complaint and not an  
15      adverse event, how did you keep track of the  
16      high number of product complaints?

17              A       Well, all -- again, all of the  
18      initial complaints, whether they were adverse  
19      or technical in nature, were always received  
20      by the medical affairs group, who would triage  
21      it. So there were always -- there was really  
22      no set way for us to determine what was a  
23      product complaint or what was an adverse event  
24      because it was all scanned into one drive. So

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1 it was the order that we processed them.

2 Q If you wanted to go back and look  
3 for a product complaint by the complaint  
4 number, is there any way to tell from the  
5 number if it was a product complaint or if it  
6 was an adverse event?

7 A No.

8 Q And was there any way for you to  
9 search all the documents as scanned into the  
10 drive, as you said, or would you have to open  
11 up individual documents?

12 A You would have to open up individual  
13 documents.

14 Q Was there a reason at any time or  
15 need on your part to go in and review product  
16 complaints after they were scanned in?

17 A Myself?

18 Q Yes.

19 A No, I never reviewed the scanned  
20 documents until they were processed and ready  
21 for my review and approval.

22 Q Once you did your review and  
23 approval, was the completed, final document  
24 scanned back in as well?

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1           A     I believe so.

2           Q     Was there a software that controlled  
3     that document or was it just, again, a scanned  
4     document that had to be opened up  
5     individually?

6           A     Again, the only files that were  
7     scanned were most probably the ones that had  
8     to be sent back to medical affairs.  
9     Otherwise, again, we always maintained the  
10    hard copy.

11                   MR. MILLER: I'm going to hand  
12    you what I'm going to mark as  
13    Exhibit 223.

14                   (Patient's Exhibit No. 223  
15    was marked for identification.)

16                   MR. ANDERTON: 223?

17                   MR. MILLER: It is 223.

18                   MR. ANDERTON: Thank you.

19    BY MR. MILLER:

20           Q     Actavis Document 0098099. And after  
21    you've had a chance to review it, ma'am, I'll  
22    have a question for you.

23                   Ma'am, I'll represent to you it's an  
24    e-mail from Anthony Castellazzo, Tuesday,

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1 September 16th, 2008, and it's to several  
2 individuals. And do you see where you are one  
3 of the recipients?

4 A Yes.

5 Q Okay. The subject is QS Assessment  
6 Status Updates. Do you recall receiving an  
7 e-mail regarding that subject?

8 A I must have. I don't recall the  
9 specifics of it.

10 Q Do you know what a QS assessment  
11 status update is?

12 A It was a quality systems assessment.

13 Q And were you involved in the quality  
14 systems assessment?

15 A To a certain extent.

16 MR. MILLER: I am going to hand  
17 you what I'm going to mark as 224.

18 (Plaintiff's Exhibit No. 224  
19 was marked for identification.)

20 BY MR. MILLER:

21 Q And if I could -- well, why don't  
22 you take a review of that document. And I've  
23 got a very specific question. You can take  
24 the time to review the entire thing if you

1 want, but it's one line I'm looking to ask you  
2 about.

3 Just to make the record clear, we'll  
4 take a look back at the original e-mail that  
5 was sent which this was the attachment to.  
6 Take a look at Document 223. And Anthony  
7 Castellazzo is sending to you and others. And  
8 it reads: "The attached file contains  
9 spreadsheets for all 6 assessed QS areas.  
10 There will be no meeting this week, therefore  
11 please provide updates via e-mail for all  
12 items that you are designated as the  
13 'Responsible Person.'"

14 And do you recall being the  
15 responsible person on any of these designated  
16 areas?

17 A I see my name on them. I don't  
18 specifically recall.

19 Q All right. We'll take a look at the  
20 QSIP, the quality systems improvement. And  
21 the line that has your name on it that I'd  
22 like to ask you about is on Page 20 of 21,  
23 Actavis 098120.

24 Ma'am, I'd like to ask you about

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1 entry -- it's No. 19, Observation 17. And  
2 under the Responsible Person, it's  
3 M. Sherwani. And that's you; correct?

4 A Correct.

5 Q Okay. And this says the target  
6 completion date was 11 September. And if we  
7 review the observation, it's: "Review of the  
8 recall file for the 2008 Digoxin recall found  
9 that the failure investigation was incomplete.  
10 The root cause of the double-thickness tablets  
11 was determined to most likely be caused by  
12 inadequate clearance of either the tablet  
13 deduster or metal detector, in spite of the  
14 fact that both pieces of equipment are located  
15 after the tablet press. There was no mention  
16 how the tablets may have gotten re-introduced  
17 into the press; and no evaluation of either  
18 the feed or dosing systems, or the ability of  
19 the press to eject fully-pressed tablets."

20 Did I read that correctly, ma'am?

21 A Yes.

22 Q And the action item, Column F, (1)  
23 is to evaluate the need for an addendum to  
24 this investigation.

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1 Do you recall being the responsible  
2 person for that action item?

3 A I see my name on it. I don't --  
4 again, as I indicated, I don't recall the  
5 specifics.

6 Q Do you recall looking at all -- do  
7 you have any memory of looking or evaluating  
8 the need for an addendum to the investigation?

9 A Honestly, no, I don't. I don't  
10 recall what took place, no.

11 Q Do you recall having anyone that you  
12 worked with or did you ask anyone to assist  
13 you with that action item?

14 A I don't even know -- I can't -- I  
15 can't answer you because I don't know what was  
16 done. I don't recall specifics as to how we  
17 addressed this observation.

18 Q I'm going to hand you what I'm going  
19 to mark as Exhibit 225.

20 The page is out, so we have to quit  
21 now.

22 A Really?

23 MR. ANDERTON: I'll hide them.

24 MR. THOMPSON: Don't make him

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1           lose his place or we have to start over.

2                       MR. ANDERTON: That could be  
3           fun to watch.

4                       (Plantiff's Exhibit No. 225  
5           was marked for identification.)

6 BY MR. MILLER:

7           Q     Ma'am, this is Actavis  
8     Document 00419719. The top line, you agree,  
9     is an e-mail from you to Abita Nanda?

10          A     Correct.

11          Q     Who is Abita?

12          A     She's a friend of mine and an  
13     ex-colleague.

14          Q     And I see Roche.com, so she used to  
15     work with you at Roche?

16          A     Correct.

17          Q     If we go down to halfway down the  
18     first e-mail starting this e-mail chain, it's  
19     from Abita Nanda to you. And it's an article  
20     titled "Congress Probes FDA's Inspection  
21     Process of Actavis."

22                       Did you get a chance to review that  
23     article?

24          A     Yes.

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1 Q And your reply to Abita Nanda was:  
2 Now I'm getting worried, bold, with a frown  
3 face; is that correct?

4 A Okay. Yes.

5 Q Is that correct?

6 Do you recall typing that to her?

7 A No, but I did.

8 Q Do you recall what you might have  
9 been worried about?

10 A I don't recall. I think it was just  
11 the fact that this is the same time that there  
12 was an issue with Ranbaxy, another  
13 pharmaceutical company, and their issues at  
14 one of their facilities in India. And this  
15 individual, Representative Dingell, he was  
16 involved in the same -- he was highly  
17 concerned, I suppose, about the recent  
18 observations that the -- one of the Indian  
19 facilities of Ranbaxy had. And I think he was  
20 just trying to lump Actavis into the same sort  
21 of general -- basically he was trying to link  
22 Actavis and Ranbaxy as having the same issues.

23 Q Was Actavis having CGMP compliance  
24 issues starting -- or strike that.

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1                   Would you agree with the statement  
2           that Actavis had a history of CGMP compliance  
3           leading up to the recall of Digitek?

4           A     I'm sorry. Can you state that  
5           again.

6                   MR. MILLER: Would you read  
7           that back.

8                   (The court reporter read the  
9           preceding question.)

10                  THE WITNESS: A history of CGMP  
11           compliance?

12           BY MR. MILLER:

13           Q     Issues. Did I not say that? There  
14           you go.

15                  MR. ANDERTON: No.

16                  MR. MILLER: All right. You  
17           got me there.

18           BY MR. MILLER:

19           Q     Would you agree with the statement  
20           that Actavis had a history of CGMP compliance  
21           issues leading up to the recall of Digitek?

22                  MR. ANDERTON: Objection.

23                  You may answer.

24                  THE WITNESS: What do you mean

1 by "issues"?

2 BY MR. MILLER:

3 Q Violations.

4 A In regards to?

5 Q CGMP.

6 A Would I agree they had a history? I  
7 don't -- I don't recall specifics. As I  
8 indicated to you before, there had been  
9 warning letters and -- but I don't know what  
10 you're requesting specifically.

11 Q You agree that they had inspections  
12 where observations were pointed out by the  
13 FDA?

14 A Correct.

15 Q Observations of CGMP violations?

16 MR. ANDERTON: Objection;  
17 mischaracterizes facts in evidence and  
18 documents.

19 You may answer.

20 THE WITNESS: Not necessarily  
21 violations. There are observations.  
22 Observations are not necessarily  
23 violations.  
24

1 BY MR. MILLER:

2 Q Not necessarily, but you agree that  
3 they certainly can be?

4 MR. ANDERTON: Objection.

5 You may answer.

6 THE WITNESS: I'm sorry?

7 BY MR. MILLER:

8 Q Observations can certainly be  
9 violations; you agree with that?

10 A Not necessarily. Observations are  
11 just an inspector's interpretation of whatever  
12 the surrounding events may be.

13 Q If you violate a CGMP, how does the  
14 FDA typically relate that information to the  
15 company?

16 A I'm not sure what you're asking.  
17 How does an FDA inspector relay the fact that  
18 a company has violated policies?

19 Q Yes.

20 A There are several means.

21 Q Is an FDA 483 inspection a report  
22 that follows that inspection? Is that a way?

23 A That may be one way. But, again,  
24 like I said, not all observations are

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1 violations. So...

2 Q Not all observations are. Some  
3 observations are violations; you just have to  
4 look --

5 A They may be.

6 Q They may be. You'd have to look  
7 into each individual observation?

8 A Absolutely.

9 Q Why did it come to be that you  
10 terminated your employment with Actavis?

11 A I received a better opportunity.

12 MR. MILLER: Give me five  
13 minutes.

14 THE VIDEOGRAPHER: Off the  
15 record at 2:05 p.m.

16 (Short recess.)

17 THE VIDEOGRAPHER: Back on the  
18 record at 2:20 p.m.

19 BY MR. THOMPSON:

20 Q Ms. Sherwani, my name's Fred  
21 Thompson. And I really have just two -- well,  
22 one subject area to ask you about. If you  
23 recall the draft press release, I think it's  
24 219, Exhibit 219, okay, now, I think you had

1 mentioned you had been asked to write a draft  
2 of press release and that it was reviewed by a  
3 series of reviewers who may have made changes  
4 but that's not part of this. This is  
5 obviously a draft because it has blanks for  
6 certain dates on it. You see that?

7 A Yes.

8 Q The thing I'm interested in is that  
9 the date on that draft press release is  
10 April 24, 2008.

11 Do you see that?

12 A Yes.

13 Q Now, is that at or about the time  
14 that it was drafted, or is that at or about  
15 the time that it was supposed to be released,  
16 if you remember?

17 A I believe it was actually being  
18 drafted on the 24th of April.

19 Q Can we say that as of April 24,  
20 2008, Actavis intended to have a voluntary  
21 recall of one lot of Digitek tablets,  
22 .125 MCG? Do you see that Lot 70924A2?

23 A Correct.

24 Q So when you drafted this press

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1 release, your instruction was that there was  
2 going to be one lot recalled; isn't that  
3 right?

4 A Correct.

5 Q Now, if I look at the top sheet,  
6 there's sort of an e-mail that says, more or  
7 less, hold the presses; the FDA has just  
8 communicated that we need to recall all lots  
9 of digoxin tablets, all strengths.

10 Do you see that?

11 A Correct.

12 Q And the e-mail is dated April 24 at  
13 2:41 p.m. Can we be assured that that's  
14 approximately the time that you wrote the  
15 e-mail?

16 A Yes.

17 Q Now, what was the reason that the  
18 FDA determined that Actavis needed to recall  
19 all lots of digoxin tablets?

20 A I don't know. I wasn't privy to  
21 that conversation.

22 Q Okay. And you were never part of a  
23 group that had that explained to them?

24 A I'm sorry?

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1           Q     You were never part of a group or a  
2 meeting or an e-mail chain that had that  
3 explained to you?

4           A     It might have been in conversation;  
5 but as I indicated, my instruction was that it  
6 had been expanded to include all batches based  
7 on a conversation that Robert Wessman had with  
8 the FDA.

9           Q     Now, you were going to have a large  
10 undertaking to recall one lot of Digitek;  
11 isn't that right?

12                   MR. ANDERTON:   Objection.

13                   You may answer.

14                   THE WITNESS:   What do you mean  
15 by "large undertaking"?

16 BY MR. THOMPSON:

17           Q     Well, I mean that was going to cause  
18 you a lot of work to undertake that and to  
19 accomplish that recall program, wouldn't it?

20           A     I'm not sure what you mean by "a lot  
21 of work."

22           Q     Okay. I guess my question is: To  
23 recall all lots of Digitek and then within the  
24 month to recall all lots of all products made

1 by the Actavis Totowa facility was an enormous  
2 expansion of your work, wasn't it?

3 MR. ANDERTON: And it's also a  
4 misrepresentation of facts in evidence.  
5 I object.

6 You may answer.

7 THE WITNESS: Can you ask the  
8 question again?

9 BY MR. THOMPSON:

10 Q I guess I'm confused because  
11 Mr. Anderton has caused me to doubt my memory,  
12 but I thought you said that you had requested  
13 additional people because of additional work  
14 that you were having to undertake.

15 A No. My statement to the question  
16 before, I believe, was specific to  
17 investigations. And then I believe, if memory  
18 serves me right, it was who I -- if I had any  
19 additional help to process the complaints. I  
20 didn't mention anything about recall.

21 Q Okay. So the scope of the recall  
22 would not add to or subtract from your work;  
23 is that right?

24 A I'm not sure -- I'm sorry. I'm not

1 understanding what you're asking.

2 Q My question is: If the recall was  
3 limited to one lot or if the recall was  
4 expanded to include all drug products  
5 manufactured by the Little Falls facility over  
6 a two-and-a-half-year period, neither of those  
7 options would subtract from or add to your  
8 workload?

9 MR. ANDERTON: Objection; form.  
10 You may answer.

11 THE WITNESS: I was requested  
12 to help with the recall activities, given  
13 my prior experience. There were other  
14 individuals and other resources that were  
15 also provided and who, once I had to deal  
16 with other priorities, that they were  
17 able to carry out the recall  
18 requirements.

19 BY MR. THOMPSON:

20 Q Now, am I hearing that you were, in  
21 fact, asked to assist with the recall?

22 A Which recall?

23 Q Well, that's where we're headed to.

24 A Okay.

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1           Q     But I understood your answer to mean  
2     that part of your job task was that you were  
3     asked to assist with the recall because of  
4     your prior experience?

5           A     Correct.

6           Q     Now, let me ask the question again.  
7     Did the scope of the recall, instead of a  
8     single lot of Digitek, it being all Digitek  
9     products and all products manufactured by the  
10    Little Falls facility, did the scope of the  
11    recall add to or subtract from your workload?

12                   MR. ANDERTON:  Objection.

13                   You may answer.

14                   THE WITNESS:  It was  
15     additional -- it was additional activity  
16     that I needed to perform.

17   BY MR. THOMPSON:

18           Q     Now, given that, were you not  
19     curious as to the reason why the press release  
20     that you drafted that encompassed one lot was  
21     expanded to be an entire facility-wide recall  
22     of all products?

23                   MR. ANDERTON:  Objection;  
24     mischaracterizes that document,

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1 mischaracterizes facts in evidence.

2 You may answer.

3 THE WITNESS: I'm sorry. Can  
4 you ask the question again.

5 MR. THOMPSON: Can you read  
6 that back for me, please.

7 (The court reporter read the  
8 preceding question.)

9 MR. ANDERTON: And same  
10 objection. That press release has  
11 nothing to do with the other product  
12 recalls.

13 MR. THOMPSON: All right.  
14 Well, let me rephrase the question.

15 BY MR. THOMPSON:

16 Q Taking the information that you had  
17 at the time that you drafted this recall  
18 notice on April 24, 2008, we're in agreement  
19 that you drafted it for a single lot of  
20 Digitek; isn't that right?

21 A Correct.

22 Q After this press release was drafted  
23 but before it was enacted, you were given the  
24 word that there would be a recall of all lots

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1 of digoxin; isn't that right?

2 A Correct.

3 Q And, in fact, within the month, all  
4 lots of all drug products manufactured by the  
5 Little Falls plant were voluntarily recalled;  
6 isn't that right?

7 MR. ANDERTON: Objection;  
8 mischaracterizes facts in evidence.

9 THE WITNESS: I'm sorry. I --  
10 if you could just repeat the question.

11 MR. THOMPSON: Would you read  
12 that back, please.

13 (The court reporter read the  
14 preceding question.)

15 THE WITNESS: It may --

16 MR. ANDERTON: Same -- hold on.

17 Same objection; greatly  
18 mischaracterizes facts in evidence.

19 You may answer if you know.

20 THE WITNESS: I don't know the  
21 time line. I don't know if it occurred  
22 within the month. I don't recall.

23 BY MR. THOMPSON:

24 Q Do you recall if it occurred at all?

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1 A If what occurred?

2 Q If all lots were recalled.

3 A All lots of what?

4 Q Of all drug products of the  
5 Little Falls plant.

6 A That's not accurate.

7 Q Okay. What is accurate then? What  
8 happened to all the lots that were produced?  
9 Not to the consumer level; it was not a Class  
10 I recall. But how would you characterize the  
11 action that was taken by Actavis Totowa with  
12 regard to all drug products manufactured by  
13 the Little Falls plant?

14 A The majority of them were recalled,  
15 but not all products that were processed in  
16 the Little Falls facility were recalled.

17 Q Okay. So my problem is that I said  
18 "all" and that's incorrect?

19 A Correct.

20 Q Okay. Now, with regard to the  
21 decision to recall all lots of Digitek and  
22 with regard to the decision within a period of  
23 time thereafter to recall certain or many of  
24 the other products manufactured by the Little

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1 Falls plant, did you -- strike that.

2 With regard to these actions, the  
3 recall of the all lots of Digitek, with regard  
4 to the recall of many of the other lots, were  
5 you curious as to the reason for such a wide  
6 recall?

7 MR. ANDERTON: Objection; form.  
8 You may answer.

9 THE WITNESS: I'm not sure what  
10 you mean by "curious." Given my role,  
11 there was a certain understanding of why  
12 certain products were being recalled  
13 voluntarily.

14 BY MR. THOMPSON:

15 Q And what was your understanding?

16 MR. ANDERTON: Objection. I  
17 instruct the witness to answer only with  
18 respect to Digitek.

19 BY MR. THOMPSON:

20 Q Let me ask you a couple questions  
21 about that. How much of your day was spent  
22 with regard to the Digitek recall?

23 A I don't recall.

24 Q Was it 90 percent of your day? Was

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1       it 10 percent? Was it half?

2           A       I don't -- it varied depending on  
3       the day.

4           Q       Okay. In fact, were you assigned  
5       Digitek as your responsibility?

6           A       In regards to?

7           Q       Was there anything special and  
8       unique about the Digitek recall that differed  
9       from the recall of all the other products that  
10      were recalled?

11          A       Were there any differences?

12          Q       Was there anything that made Digitek  
13      special and unique with regard to the other  
14      products?

15                   MR. ANDERTON: Objection.

16                   You may answer if you  
17      understand.

18                   THE WITNESS: I'm not quite  
19      sure I do understand what you're asking  
20      me.

21      BY MR. THOMPSON:

22          Q       Was there anything that made your  
23      handling of the Digitek recall different than  
24      your handling of any of the other

1 contemporaneous recalls that were undertaken  
2 at the --

3 A All recalls are going to be handled  
4 per internal procedures and regulatory  
5 requirements.

6 Q And who does that? I mean, who did  
7 that?

8 A Who did what?

9 Q Who did all the recalls?

10 A For digoxin?

11 Q Well, no; for all of them.

12 A Well, it was a team. Some of the  
13 information for the other recalls, some of the  
14 other recalls I was working on. There were  
15 other recalls that other individuals were  
16 working on.

17 Q Now, when I hear the word "team" --  
18 as a matter of fact, I think I overheard us  
19 defining a team. A team is a group of people  
20 unified by a goal or an objective, working  
21 together collegially; you agree with that?

22 A Yes.

23 Q Was the team at Actavis working  
24 together to pursue all of the recalls of all

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1 of these products?

2 A Do you mean were they working  
3 towards completing the recall activities once  
4 the decision was made?

5 Q Yes, ma'am.

6 A Yeah, there were many individuals  
7 who were working on that.

8 Q Now, was one person assigned  
9 OxyContin and one person was assigned gel caps  
10 and one person was assigned Digitek and one  
11 person -- or did everybody work on all the  
12 recalls?

13 A Initially it was just a few  
14 individuals who were working on the recalls.  
15 Once it expanded, there was additional  
16 resources that were provided.

17 Q Well, now, in your case, I think  
18 we've already mentioned that you worked on  
19 Digitek, but you also worked on other things  
20 as well; is that right?

21 A Correct.

22 Q Did all of the drug products that  
23 were recalled, were they recalled because of  
24 departures from current good manufacturing

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1 practices?

2 MR. ANDERTON: Objection.

3 I instruct the witness to  
4 answer only with respect to Digitek.

5 Do you understand my  
6 instruction?

7 THE WITNESS: Yes.

8 The one lot of digoxin that was  
9 agreed to be recalled was as a result not  
10 so much of a departure; it was the  
11 inspector's opinion that for that one  
12 particular lot, there was -- that, you  
13 know, there may have been -- there may  
14 have been an occurrence where  
15 double-thick tablets may have been  
16 distributed to the market.

17 BY MR. THOMPSON:

18 Q Okay. That's the one lot. And I  
19 understand that lot. I don't understand all  
20 the other lots. Why were all the other lots  
21 recalled?

22 A I have no idea. As I indicated to  
23 you previously, I was told that that was the  
24 directive that the company had taken.

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1 Q Now, let's pull out the  
2 Plaintiff's 141 as well. It should be a  
3 one-page document that says "Investigation."

4 MR. ANDERTON: Right there.

5 You had it.

6 THE WITNESS: Okay.

7 BY MR. THOMPSON:

8 Q Now, this was the lot that was the  
9 subject of that e-mail correspondence back and  
10 forth between various people. And this was  
11 the lot that had been released to Mylan but  
12 had been captured en route, and so it did not  
13 reach the consuming public. Okay?

14 MR. ANDERTON: Objection.

15 BY MR. THOMPSON:

16 Q I think we're in agreement to that.

17 MR. ANDERTON: Objection. I  
18 think nobody's in agreement to that.  
19 That is a deliberate mischaracterization  
20 of facts and evidence.

21 MR. THOMPSON: All right.

22 BY MR. THOMPSON:

23 Q Was this lot released to Mylan?

24 A No.

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1 Q Oh, you are exactly right.

2 Mr. Anderton is exactly right. I'm wrong  
3 about that.

4 Pull out Plaintiff's 142.

5 MR. ANDERTON: We wouldn't have  
6 let the record stand wrong for long.

7 BY MR. THOMPSON:

8 Q Pull out Exhibit 142 as well. I  
9 apologize.

10 A I have it.

11 Q I was misreading that the 80202A,  
12 80228A. So let's look at the Plaintiff's 141  
13 first. Okay?

14 Now, this is an Investigation 08-060  
15 and it is -- it says Control Number 80228A1.  
16 Now, is that the same as a lot number?

17 A Correct.

18 Q Now, in this batch or this lot, the  
19 tablets weighed out of spec; isn't that right?

20 A I believe it indicates that the  
21 filled bottle weight was going higher than the  
22 set range.

23 Q And it looks like the packing  
24 manager or the PKG manager took random sample

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1 tablets and checked the weight.

2 Do you see that?

3 A Correct.

4 Q And it looks like he checked 30; and  
5 out of 30, 17 of them were higher weight.

6 Do you see that?

7 A Yes.

8 Q Now, this lot number has nothing to  
9 do with the lot number that had the  
10 double-stamped pills, does it?

11 A Which lot are you referring to?

12 Q The lot that was the subject of your  
13 draft press releases, Lot No. 70924A2; right?

14 A Yes.

15 Q And this lot is Lot 80228A; right?

16 A Correct.

17 Q And when these guys are talking  
18 about higher weight, they're talking about a  
19 weight that's above the range that's allowed  
20 per pill. They're not talking about a  
21 double-thickness pill; aren't we right about  
22 that?

23 A That's what it indicates, yes.

24 Q Now, Lot 80228A, will you agree that

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1       that lot was manufactured in violation of  
2       current good manufacturing practice?

3                       MR. ANDERTON: Objection.

4                       You may answer.

5                       THE WITNESS: I don't agree  
6       that it was -- I don't agree.

7       BY MR. THOMPSON:

8               Q     You believe that current good  
9       manufacturing practice would permit the  
10      manufacture of a lot of pills in which 17 of  
11      30 tablets would measure out above the  
12      120-milligram weight against target weight of  
13      105?

14              A     I'm sorry. Can you repeat the  
15      question?

16              Q     You believe that a lot in which 17  
17      of 30 tablets were found to be of a weight  
18      higher than the accepted range would be within  
19      current good manufacturing practice standards?

20              A     It depends. I'd have to have more  
21      information about the issue before I make a  
22      determination.

23              Q     What additional information would  
24      you, as the senior manager of quality

1 assurance, what would you need to decide that  
2 17 out of 30 tablets above specification was  
3 not in violation of current good manufacturing  
4 practice?

5 A Well, there are criteria. You have  
6 an AQL, which is an acceptance quality --  
7 basically an acceptance level that is  
8 prescribed. So I don't know what the AQL for  
9 this particular batch was. I would need to  
10 know what the in-process checks and other  
11 processing parameters were before I made that  
12 determination.

13 Q Okay. In any event, are we in  
14 agreement that we're not talking about  
15 double-stamped pills here?

16 A It just indicates that it's an issue  
17 with weight. I don't see anything about  
18 thickness here.

19 Q All right. Would you agree that the  
20 production of Digitek at Actavis Totowa was  
21 plagued with systemic deviations from current  
22 good manufacturing practices for the period  
23 2006 through April of 2008?

24 MR. ANDERTON: Objection.

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1                   You may answer.

2                   THE WITNESS: I can only speak  
3                   to when I was in employment at Actavis,  
4                   which was from January 2008 to October of  
5                   2009.

6                   MR. THOMPSON: Okay. Thank you  
7                   very much. I appreciate your time.

8                   MR. ANDERTON: We're not done.  
9                   I'm going to ask some questions. Let's  
10                  go off the record.

11                  THE VIDEOGRAPHER: Off the  
12                  record, 2:45 p.m.

13                  (Short recess.)

14                  THE VIDEOGRAPHER: Back on the  
15                  record at 2:48 p.m.

16                  BY MR. ANDERTON:

17                  Q     Ms. Sherwani, my name is Michael  
18                  Anderton. I'm here on behalf of the Actavis  
19                  defendants. And I am going to take a few  
20                  minutes to ask you some questions as well.  
21                  Okay?

22                  A     Sure.

23                  Q     And I'll be brief on each subject.  
24                  Will you find in your pile of exhibits

1 Exhibit 222? It's the product complaint form  
2 that you gave some testimony about previously.  
3 Right there.

4 Do you remember Mr. Miller, I  
5 believe, asked you about the product numbering  
6 or -- I'm sorry -- the complaint numbering set  
7 forth at the top right corner of this first  
8 page?

9 A Yes.

10 Q And asked you to confirm that the  
11 3790 indicated that that's the 3,790th  
12 complaint for 2008?

13 A Correct.

14 Q How many of the Digitek  
15 complaints -- you gave some earlier testimony  
16 about the volume of Digitek complaints. What  
17 is your experience or what was your experience  
18 about the volume of Digitek product complaints  
19 pre recall versus post recall of Digitek?

20 A Oh, it was in -- phenomenal. There  
21 were -- prior to the recall, there were  
22 perhaps a handful; whereas, after the recall,  
23 it just skyrocketed.

24 Q So, for example, the 3,790

1 complaints or 3,789 complaints that preceded  
2 the one that is reflected in Exhibit 222, do  
3 you have a recollection of approximately how  
4 many, what percentage of those were Digitek  
5 complaints?

6 A The majority of them were Digitek  
7 complaints.

8 Q Well, the majority could be  
9 51 percent. Was it higher than --

10 A Yeah, it was definitely higher. I  
11 would probably say 95-plus percent post recall  
12 were related to digoxin.

13 Q And of those 95 percent that were  
14 digoxin-related, how many of those were post  
15 recall?

16 A The majority of them.

17 Q Again, the majority, is that over  
18 half or is it --

19 A Oh, absolutely, yes.

20 Q You talked about -- and I know  
21 you've now been asked questions by Mr. Miller  
22 and Mr. Thompson about the expansion of the  
23 Digitek recall from one lot to a single lot.  
24 You've given some testimony about your

1 involvement and about a conversation or a  
2 statement you made in an e-mail about the  
3 recall expanding from one lot to all lots. I  
4 did want to follow up on that and ask a few  
5 additional questions just to make sure the  
6 record is clear, at least in my mind.

7 When you testified about it, about  
8 the recall initially, you testified that the  
9 decision to recall Digitek was a voluntary  
10 decision made by the company; correct?

11 A Correct.

12 Q When you spoke with the FDA -- well,  
13 let me strike that.

14 The decision to expand it from a  
15 single lot to all lots, was that a voluntary  
16 decision made by the company?

17 A Let me clarify that.

18 Q Please.

19 A Where I was involved, I actually  
20 received a call from the recall coordinator  
21 that indicated to me that I had to issue a  
22 press release not just for that one lot, but  
23 we were going to have to expand the recall to  
24 all lots for both strengths.

1                   And I was taken aback. I asked why.  
2                   And I never got a reason except the recall  
3                   coordinator from the FDA indicating that she  
4                   had spoken to Robert Wessman and he had agreed  
5                   to the voluntary recall of all lots.

6                   Q     You gave some testimony about filing  
7                   field alert reports. Do you remember that  
8                   testimony?

9                   A     Yes.

10                  Q     Under what circumstances, again,  
11                  generally -- first, under what circumstances  
12                  to the extent you were involved in filing  
13                  field alert reports, what would prompt the  
14                  company to file a field alert report?

15                  A     A field alert report is issued when  
16                  you have a significant quality issue related  
17                  to a lot or lots of product that have been  
18                  distributed to the market.

19                  Q     So product that is in the market?

20                  A     Correct.

21                  Q     If you have a quality issue that  
22                  doesn't -- that doesn't relate to product that  
23                  was distributed to the market, to defective  
24                  product that was distributed to the market,

1 would that require filing a field alert  
2 report?

3 A No.

4 Q So if you have an  
5 out-of-specification result, for example, you  
6 identify the out-of-specification result and  
7 deal with it from a quality assurance  
8 perspective and that product -- and no  
9 defective product goes to market, would you  
10 issue a field alert report in that context?

11 A No. Unless it's marketed to --  
12 unless it's distributed to the market, it is  
13 not the subject of a field alert.

14 Q Thank you. Will you find  
15 Exhibit 217 and at the same time Exhibit 141.

16 All right. Exhibit 217 is an e-mail  
17 that -- well, it includes two e-mails, as I  
18 read it, but the last of which is an e-mail  
19 from you -- and I don't have the correct copy,  
20 but I think it was Chris Jensen. I don't have  
21 the correctly marked copy -- dated April 15,  
22 2008; correct?

23 A Yes.

24 Q And in that e-mail, you forwarded

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1 to -- and I'm sorry. Who did you send that  
2 to? That's missing from that copy as well.

3 MR. ANDERTON: Where is your  
4 copy of 217, Mr. Miller? Just so I  
5 can -- can I work from that for the  
6 moment?

7 MR. MILLER: I don't believe  
8 any of them have the "to" line.

9 MR. ANDERTON: One of them did.  
10 One of them did.

11 MR. MILLER: I don't believe  
12 so. Can I get my copy back?

13 MR. ANDERTON: Yes, you can.

14 BY MR. ANDERTON:

15 Q And you testified about the  
16 attachment. Do you remember talking about the  
17 attachment that reflects investigations that  
18 had been -- that had occurred from  
19 September 5, 2007, up to sometime prior to  
20 you -- to the time you sent this?

21 A Yes.

22 Q The attachment to your April 15  
23 e-mail, do you know when that was actually  
24 created?

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1 A No, I don't. I don't recall.

2 Q So you don't know the cutoff date,  
3 if you will, for investigations and what could  
4 be included, what would be excluded just  
5 because it might have been started at or after  
6 the time this list was created?

7 A Agreed.

8 Q And turning to Exhibit 141, does  
9 that document indicate the date of occurrence  
10 for the underlying circumstances?

11 A Yes.

12 Q And what is that date?

13 A April 1st, 2008.

14 Q And "date of occurrence" means what?

15 A The date that the supposed  
16 discrepancy occurred.

17 Q And does that mean that's the date  
18 the investigation was opened?

19 A Not necessarily.

20 Q How long typically after that until  
21 an investigation is opened?

22 A It honestly depends on when the  
23 discrepancy was observed or noticed by  
24 someone.

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1           Q     Okay. Well, assuming that the  
2           occurrence -- well, all right. Is there any  
3           way to tell whether the attachment in  
4           Exhibit 217 was prepared after or before the  
5           occurrence and the investigation opened in --  
6           before Investigation 08-060 was opened?

7           A     No, I can't. No.

8           Q     I want you now to find,  
9           Ms. Sherwani, the Exhibits 220 and 221,  
10          please, and I'm going to ask you some  
11          questions about those.

12                     Exhibit 220 is a cover letter from  
13          the office of Dr. Leikin with the attached  
14          Digitek or digoxin health hazard evaluation.

15                     Do you remember testifying about  
16          those documents?

17          A     Yes.

18          Q     If you look at the health hazard  
19          evaluation that is attached to the cover  
20          letter from Dr. Leikin's offices that is part  
21          of Exhibit 220 -- well, looking at both of  
22          these documents together, is there any way to  
23          tell when the company received this health  
24          hazard evaluation?

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1           A     Well, I mean, the first page  
2     indicates that it was sent via FedEx on  
3     April 25th.

4           Q     Sent via Federal Express overnight;  
5     correct?

6           A     Correct.

7           Q     So the earliest the company could  
8     have received that health hazard evaluation  
9     was April -- the one that's attached to this  
10    letter was April 26th, 2008?

11          A     That would be right.

12          Q     Okay. And turning to Exhibit 221  
13    now, do you remember giving some testimony  
14    about the recall package?

15          A     Yes.

16          Q     If you would turn to Bates Page  
17    No. 28213, and you remember that that is the  
18    press release the company issued. What's the  
19    date of that press release?

20          A     April 25th.

21          Q     Is that before the company received  
22    the health hazard evaluation that is set -- or  
23    that is part of Exhibit 220?

24          A     It appears to be, yes.

1           Q     Turning to Bates Page 28208 of the  
2 recall packet, which is Exhibit 221, do you  
3 remember giving some testimony about that  
4 document?

5           A     Yes.

6           Q     What's the date of that document?

7           A     April 28th, 2008.

8           Q     Is that after the company received  
9 the health hazard evaluation that is part of  
10 Exhibit 220?

11          A     It would appear to be, yes.

12          Q     And does the document that is -- or  
13 I'm sorry. Yeah. Does the document that is  
14 set forth at Bates Page 28208, does it contain  
15 the additional language Mr. Miller was asking  
16 you questions about with respect to, as  
17 Mr. Miller put it, identifying potentially two  
18 different classes of people?

19               And if you need a moment to compare  
20 the two, please do.

21          A     Yes.

22          Q     So Mr. Miller focused on the -- and  
23 I want to get this correct -- the second  
24 sentence of the fourth paragraph of the health

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1 hazard evaluation that refers to the two  
2 classes of people being those with renal  
3 insufficiency or those taking daily doses.

4 A Correct.

5 Q The same language appears in the  
6 April 28, 2008, document that the company  
7 prepared after receiving this health hazard  
8 evaluation, doesn't it?

9 A Yes.

10 MR. ANDERTON: I have no  
11 further questions. Thank you. I'm sure  
12 Mr. Miller will have a few more now that  
13 I've --

14 MR. MILLER: I do. Five  
15 minutes.

16 BY MR. MILLER:

17 Q Ma'am, only a couple of follow-up  
18 questions on going back to the recall package  
19 that you signed and approved for the FDA on  
20 May 23rd of 2008. I believe you have a copy  
21 of it in front of you?

22 A Yes.

23 Q Am I correct in saying that all  
24 these documents were together, all

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1        attachments, when you approved this on  
2        May 23rd of 2008?

3            A        Yes.

4            Q        So if we look at Actavis  
5        Page 0028213, you would agree with me that you  
6        approved this document with this news release  
7        that included the line in the third paragraph  
8        that starts with "Digitek": "Digitek is used  
9        to treat heart failure and abnormal heart  
10       rhythms"; the next sentence being: "The  
11       existence of double strength tablets poses a  
12       risk of digitalis toxicity in patients with  
13       renal failure"?

14                    And you agree that you approved this  
15       document with this statement when, in fact,  
16       you did have a copy of the health hazard  
17       evaluation from Dr. Leikin; is that correct?

18                    MR. ANDERTON:    Objection;  
19       mischaracterizes the facts.

20                    You may answer.

21                    THE WITNESS:    I'm sorry.    I'm  
22       not understanding.

23                    MR. MILLER:    Would you read  
24       that back, please.

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1 (The court reporter read the  
2 preceding question.)

3 THE WITNESS: I don't -- again,  
4 this press release was issued on  
5 April 25th of 2008.

6 BY MR. MILLER:

7 Q Yes.

8 A And apparently this health hazard  
9 assessment was received by Actavis, based on  
10 the copy that I have here, around April 26th.

11 Q Okay. And my -- but if you look --  
12 look at Actavis 28205.

13 A Okay.

14 Q 28205.

15 A Oh, 205. I'm sorry. Okay.

16 Q And that is an attachment,  
17 Attachment V, which you would agree is a copy  
18 of the health hazard evaluation; correct?

19 A Correct.

20 Q And you had this document on  
21 May 23rd when this recall package was approved  
22 by you?

23 A I had the copy of this health hazard  
24 evaluation, yes.

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1           Q     And at the same time you also had a  
2     copy of the news release as part of this  
3     recall package?

4           A     Yes.

5           Q     You were asked what would prompt a  
6     field alert. And correct me if I'm wrong, but  
7     I believe you stated that it would be a  
8     significant quality issue with a product that  
9     was distributed to the market; is that  
10    correct?

11          A     Correct.

12          Q     Is that also a valid reason to  
13    conduct a recall?

14          A     Not necessarily.

15          Q     Was Digitek recalled because there  
16    was a significant quality issue with the  
17    product that was distributed to the market?

18                   MR. ANDERTON: Objection; asked  
19    and answered multiple times.

20    BY MR. MILLER:

21          Q     It's okay to answer.

22                   MR. ANDERTON: You may answer  
23    if you know.

24                   THE WITNESS: I don't know the

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1 reason.

2 MR. MILLER: That's all I have.

3 MR. ANDERTON: No, no further  
4 questions from me.

5 THE VIDEOGRAPHER: This  
6 completes Videotape 3. Off the record at  
7 3:08 p.m.

8 (Whereupon the deposition  
9 adjourned at 3:08 p.m.)

10 - - -

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CERTIFICATE

I HEREBY CERTIFY that the  
witness was duly sworn by me and that the  
deposition is a true record of the testimony  
given by the witness.

It was requested before  
completion of the deposition that the witness,  
MISBAH SHERWANI, have the opportunity to read  
and sign the deposition transcript.



---

KIMBERLY A. OVERWISE  
Certified Realtime Reporter  
Notary Public  
Dated: March 30, 2010

(The foregoing certification of  
this transcript does not apply to any  
reproduction of the same by any means, unless  
under the direct control and/or supervision of  
the certifying reporter.)

## 1 INSTRUCTIONS TO WITNESS

2  
3 Please read your deposition over  
4 carefully and make any necessary corrections.  
5 You should state the reason in the appropriate  
6 space on the errata sheet for any corrections  
7 that are made.

8 After doing so, please sign the  
9 errata sheet and date it.

10 You are signing same subject to the  
11 changes you have noted on the errata sheet,  
12 which will be attached to your deposition.

13 It is imperative that you return the  
14 original errata sheet to the deposing attorney  
15 within thirty (30) days of receipt of the  
16 deposition transcript by you. If you fail to  
17 do so, the deposition transcript may be deemed  
18 to be accurate and may be used in court.

19  
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21  
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1	E R R A T A S H E E T		
2	- - - - -		
3			
4	PAGE	LINE	CHANGE
5	_____	_____	_____
6		REASON:	_____
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## ACKNOWLEDGMENT OF DEPONENT

I, MISBAH SHERWANI, do hereby  
certify that I have read the foregoing pages,  
1-222, and that the same is a correct  
transcription of the answers given by me to  
the questions therein propounded, except for  
the corrections or changes in form or  
substance, if any, noted in the attached  
Errata Sheet.

---

MISBAH SHERWANI

---

DATE

Subscribed and sworn  
to before me this  
\_\_\_\_ day of \_\_\_\_\_, 2010.

My commission expires: \_\_\_\_\_

---

Notary Public

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1	LAWYER 'S NOTES		
2	PAGE	LINE	
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4	_____	_____	_____
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